U.S. Department of Energy
Office of Price-Anderson Enforcement

Enforcement Program Plan

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I. Purpose

This Program Plan describes the processes used by the Department of Energy (DOE or Department) Office of Price-Anderson Enforcement (OE) in implementing its regulatory obligations under:

- The *General Statement of Enforcement Policy* in 10 CFR Part 820, appendix A, as amended, for violations of nuclear safety requirements, and
- The *General Statement of Enforcement Policy* in 10 CFR Part 851, appendix B, for violations of worker safety requirements.

To promote strong safety performance by contractors, OE is authorized to exercise considerable discretion in applying the enforcement tools at its disposal, as well as to apply mitigation when enforcement actions are taken to recognize positive performance by contactors. In brief, the DOE enforcement program is premised on "rewarding" contractors for early identification, reporting and effective correction of safety noncompliances.

This Program Plan describes factors used by OE in judging the positive steps being taken by contractors as well as the factors used in applying the enforcement sanctions. If enforcement actions are determined to be required, they are applied in accordance with the provisions of the enforcement policies noted above. It should be remembered that the purpose of the Department's enforcement policies and the application of those by OE is to improve nuclear safety for our workers and the public, and occupational safety and health for workers at DOE facilities. This goal is the prime consideration in exercising enforcement discretion and in application of mitigation.

This Program Plan supersedes the following previously-issued guidance by OE (for reference, these are still available on the OE web site through the links below):

DOE Enforcement Program Roles and Responsibilities Guidance Handbook (DOE-HDBK-1085-95)

Identifying, Reporting, and Tracking Nuclear Safety Noncompliances (Operational Procedure, June 1988)

Enforcement of DOE Nuclear Safety Requirements under Price-Anderson Amendments Act of 1988 (Operational Procedure, June 1988)

Enforcement Guidance Supplements (EGSs) issued from Enforcement Program inception through date of issue or update of this document. New EGSs issued after date of issue or update of this document will be posted on the OE website[1] until they are incorporated into the subsequent update of the Enforcement Program Plan.

The material in this Program Plan is structured to provide a common approach to both nuclear and worker safety where possible. Unless noted otherwise, this guidance applies to both areas. In some areas, guidance specific to nuclear or worker safety is provided and noted as such.

[1] http://www.eh.doe.gov/enforce/

Interim Enforcement Guidance

From time to time, enforcement issues will arise that require OE to clarify or supplement the guidance and procedures set forth in this Program Plan. Such clarifications or supplements may be issued as an update to this Program Plan or in the form of an EGS on an interim basis until the next Program Plan update. The Director, Office of Price-Anderson Enforcement, (Director) endeavors to provide such guidance in a timely manner and assure its wide distribution. Notification of such updates will generally be forwarded to DOE and contractor Price-Anderson Amendments Act (PAAA) coordinators at each site and be made available on the OE website.

Background

The *Atomic Energy Act* provides indemnification[2] to DOE contractors who manage and operate nuclear facilities in the DOE complex. In 1988, the PAAA was signed into law to continue this indemnification. The PAAA subjects DOE-indemnified contractors, subcontractors, and suppliers to potential civil penalties for violations of DOE rules, regulations, and compliance orders relating to nuclear safety requirements. As part of its agreement to continue the indemnification coverage, Congress mandated that DOE enforce nuclear safety requirements to minimize the risk to workers and the public. On August 17, 1993, DOE published its nuclear safety enforcement procedural rules and enforcement policy (10 CFR Part 820, appendix A, *General Statement of Enforcement Policy*), and this was further amended on November 7, 1997. OE has the responsibility to carry out the statutory enforcement authority provided to DOE in the PAAA. OE commenced enforcement of the nuclear safety rules in 1995.

The *Bob Stump National Defense Authorization Act for Fiscal Year 2003* extended current indemnification levels until December 31, 2004, and required DOE to promulgate final rules to enforce Occupational Safety and Health requirements. The *Ronald W. Reagan National Defense Authorization Act for Fiscal Year 2005* extended indemnification until December 2006. The *Energy Policy Act of 2005* extended indemnification of DOE contractors to December 2025, increased liability coverage to $10 billion per incident, and repealed remission of civil penalties for nonprofits upon the signing of a new contract.

On February 9, 2006, DOE issued the *Worker Safety and Health Program* rule, 10 CFR Part 851, which included in subpart E the enforcement process to be applied to worker safety violations, and, in appendix B, the enforcement policy for such violations. Part 851 goes into effect on February 7, 2007, and on May 27, 2007, no work may be performed at a covered workplace unless an approved worker safety and health program is in place.

[2] By indemnifying the contractor, the government acts as an insurer against any findings of liability arising from the nuclear activities of the contractor within the scope of its contract.

II. Enforcement Philosophy

In brief, the purpose of DOE's enforcement philosophy is to enhance and protect the radiological safety of the public and workers at DOE facilities, and occupational safety and health for employees at DOE facilities, through a process that encourages the effective understanding and proper implementation of safety requirements; critical self-assessment of activities; and the timely identification, open and prompt reporting, and prompt, aggressive correction of noncompliance conditions by DOE contractors.

To paraphrase the enforcement philosophy stated in 10 CFR Part 820, appendix A (for nuclear safety) and in 10 CFR Part 851, appendix B (for worker safety):

> The single most important goal of the DOE enforcement program is to encourage early identification and reporting of nuclear safety deficiencies and violations of DOE occupational safety requirements by the DOE contractors themselves rather than by DOE, and the prompt correction of any deficiencies and violations so identified. DOE believes that the contractors are in the best position to identify and promptly correct noncompliances.

The DOE PAAA enforcement program is a civil enforcement process that focuses on the performance of contractor organizations as it relates to compliance with DOE nuclear and worker safety rules. OE does not issue enforcement actions against individual contractor employees. If OE becomes aware of the possibility of criminal behavior through any of its activities, OE will refer the issue to the U.S. Department of Justice, as further described in chapter VIII.

Enforcement Program Approach

OE applies an enforcement approach that is founded on several key elements:

- Emphasis on contractor implementation and assurance of compliance with nuclear and worker safety rules.
- Driving a continuous improvement focus, rather than acceptance of the status-quo.
- Desired contractor timely self-identification and correction of noncompliance conditions and underlying problems affecting compliance.
- Exercise of broad discretion when contractors are exhibiting the desired approach.
- Taking selective enforcement action for significant safety events or significant precursor conditions, including continued repeat events, close-calls, and general adverse safety performance.
- Periodic reviews of contractor screening and reporting processes, and selective review of compliance issues in program reviews or focused inspections.
- Stimulating contractor transition from a reactive, event-driven approach to identifying and correcting deficiencies towards a proactive, assessment-driven approach.
- Broadly sharing information on enforcement actions and identified generic safety issues to serve as lessons learned to promote proactive improvement in safety before an

enforcement action is required.

- Promoting the desired safety management and compliance assurance attributes so that excellence in safety is achieved without the need for enforcement actions. Such areas include assessment programs, safety culture, and corrective action processes.

III. Roles and Responsibilities

Significant efforts by many DOE and contractor personnel are required to assure strong safety compliance and performance, an effective self-regulatory or compliance assurance process, proper identification, reporting and resolution of noncompliances, and effective interface with the enforcement process. The following provide OE's perspective on those key roles and responsibilities.

The OE Director and staff are the principal individuals setting guidance and implementation practices for enforcement activities. Key interfaces with OE are provided by DOE Program and Field Office PAAA coordinators and their management. These coordinators are also generally the principal interface with contractors on matters involving safety rules, noncompliances, and enforcement proceedings. Contractors also designate a single individual to be their PAAA coordinator, serving as the principal interface with their corresponding DOE PAAA coordinator and OE, as well as the principal lead in the contractor organization for rule implementation, noncompliances, and enforcement proceedings. Senior contractor management personnel are also key to ensuring effective compliance with safety requirements and excellent safety performance. While some organizations or positions may not function as described herein, the following provide OE's perspective on the desired roles and responsibilities of these key positions.

Director, Office of Price-Anderson Enforcement

The Director has been designated as the principal officer for DOE enforcement activities for PAAA. The Director manages all DOE PAAA enforcement activities, directs the technical and legal reviews, supervises investigations, prepares enforcement actions, and is responsible for the administrative litigation of contested enforcement actions, the issuance of consent orders to resolve contested issues, and the appropriate referral of potential criminal enforcement actions to the Department of Justice. The Director is authorized to issue enforcement correspondence and enforcement actions, except that enforcement actions involving National Nuclear Security Administration (NNSA) facilities require the signature of the NNSA Administrator, based upon the recommendation of the Director. The Director regularly communicates to senior DOE and contractor management the state of the enforcement program and observations on safety and compliance issues identified in the enforcement program. The Director is also responsible for providing guidance and training for implementation of the Department's PAAA Enforcement Program.

Office of Price-Anderson Enforcement

OE staff perform the following tasks, among other duties:

- Review and evaluate available information on noncompliances including information reported to the Noncompliance Tracking System (NTS).
- Identify to the Director significant noncompliance conditions and recommend investigation, focused inspection, and/or enforcement action.
- As needed, conduct investigations or focused inspections associated with potential violations of DOE safety requirements, and prepare summary reports and/or technical evaluations as required.

- Participate in enforcement conferences, and may chair the enforcement conference in the absence of the Director.
- Provide recommendations during the post-conference, DOE-only discussions and deliberations. The final decision on the enforcement action rests with the Director (or NNSA Administrator for NNSA facilities).
- Inform DOE personnel of obligations to absolutely maintain planned enforcement action details and communications confidential until issuance of the action.
- Prepare for the Director's signature (or NNSA Administrator for NNSA facilities) all recommended enforcement actions, including notices of violation (NOV) and appropriate transmittal letters to the contractor, as well as draft press releases.
- Prepare for the Director's signature enforcement letters for precursor conditions that need attention, but for which an enforcement action is not being taken.
- Conduct program reviews of contractor voluntary noncompliance screening and reporting processes as well as selective compliance issues, and prepare summary reports for the Director's signature.
- Maintain the NTS.
- Maintain docket files for: enforcement actions; enforcement letters; exemptions to nuclear safety requirements issued pursuant to Part 820, subpart E; variances to worker safety requirements issued pursuant to Part 851, subpart D; and rule implementation program plans and updates. Docketing functions are performed by the OE Docketing Clerk.
- Conduct the annual training workshop to include introductory PAAA training for new DOE and contractor coordinators, and refresher training for DOE coordinators.
- Share information and guidance on enforcement actions, lessons learned, compliance issues, and other program details through various mechanisms, including the OE website, EGSs, coordinator conference calls, presentations at Energy Facility Contractor Group (EFCOG) sessions, and meetings with senior DOE and contractor managers.
- Prepare an annual report summarizing enforcement program activities over the past year, and planned activities and initiatives for the coming year.

DOE and Contractor Senior Management

For the PAAA coordinator position to function effectively and to ensure DOE achieves a high level of safety performance, both senior DOE and contractor management must take on critical enabling roles, including:

- Ensuring that safety is the number one priority, and is not trumped by the strong emphasis and contract incentives on program objectives and schedules.
- Regularly demonstrating emphasis on safety performance, compliance with safety requirements, a positive safety culture, and an ethic of continuous improvement, as well as facilitating the transition from being event-driven to being an assessment-driven organization.
- Demonstrating strong support for the PAAA screening and reporting process, assessment programs, and the corrective action process, both within the Field Office and by their contractors.

- Considering the PAAA program an integral part of the safety management program and not just a "check the box" exercise.
- Ensuring that the individual selected for the DOE PAAA coordinator position has strong credibility within the organization and with senior management.
- Placing the PAAA coordinator at a senior reporting level, demonstrating management commitment to the program, and providing access to senior management when necessary.
- Being supportive of and relying on the views of the PAAA coordinator.
- Maintaining regular and open communication with the contractor, Program Office, and OE on safety, noncompliance conditions, and NTS report resolution.

There are also critical enabling roles specific to each management group. For DOE Field Office senior management, it is important that staff be assigned to provide support to and, as needed, participate with OE in PAAA investigations or reviews.

Accordingly, contractor senior management also has the following specific critical enabling roles:

- Delegating strong authority to safety managers and the PAAA coordinator, and ensuring that clear roles for and responsibilities of the coordinator are defined.
- Driving the organization to a centralized issues management system utilized as an action-forcing mechanism for lasting, effective corrective actions.
- Driving the organization to achieve a level of performance such that few programmatic or significant safety problems are disclosed by events, i.e., most are prevented through effective contractor performance assessment activities.

DOE PAAA Coordinator

A key step within DOE to facilitating safety performance, enhancing compliance with safety requirements, and effectively interfacing with OE is the designation of a point of contact from each DOE and contractor organization. Each organization with responsibility for management or oversight of activities that come under the DOE safety rules should identify a PAAA coordinator. Examples of desired PAAA coordinator roles and responsibilities are:

- Being knowledgeable of nuclear and worker safety requirements and the enforcement process.
- Maintaining a broad understanding of the activities and operations being undertaken by their contractor/organization.
- Acting as the focal point to promote effective communications within DOE and with the contractor on PAAA matters.
- Identifying and openly communicating safety concerns and adverse trends to senior DOE and contractor management.
- Ensuring Federal managers are adequately trained in the elements of the PAAA program.
- Providing oversight of contractor identification, screening, reporting, and correction of noncompliances.
- Being knowledgeable of NTS reporting thresholds and having sensitivity for programmatic issues, negative trends, and repetitive issues.
- Collecting information or coordinating with appropriate

personnel to provide information and collaborate with OE in evaluating noncompliances reported into the NTS.

- Coordinating the identification of DOE and contractor personnel for technical support when necessary to bring an issue to closure.
- Coordinating a periodic review of noncompliances tracked locally by the contractor.
- Conducting routine oversight of the contractor's PAAA program for deficiency identification and screening, and noncompliance reporting and closure.
- Entering into NTS noncompliance conditions that the DOE coordinator believes are above the NTS reporting threshold, but which the contractor has declined to enter into NTS.
- Verifying the proper and timely completion of corrective actions (with assistance of facility representatives and subject matter experts) for NTS items.
- Entering verification results into NTS with clear recommendations for closure.
- Providing input, with their DOE management, to the enforcement process, including for any preliminary investigation strategy discussion, enforcement conference, post-conference deliberations, and framing any enforcement action.
- Actively participating in dialogues between DOE and the contractor in any investigation or compliance review to ensure the facts and technical issues surrounding the noncompliance are understood, and the impact on safety is properly considered.

Contractor PAAA Coordinator

The contractor PAAA coordinator position is a pivotal position in driving safety performance at the contractor organization. With the interface to OE, and if properly supported by senior management, the coordinator is in a position to positively influence the organization's attention to and assurance of compliance with safety requirements and to drive continuous improvement. To achieve these benefits to the organization, each contractor organization should formally designate a contractor PAAA coordinator. Examples of desired roles and responsibilities of include the following:

- Being knowledgeable of nuclear and occupational safety requirements and the enforcement process.
- Maintaining a broad understanding of the activities and operations being undertaken by their contractor/organization.
- Serving as the focal point in the contractor's organization for rule implementation and compliance, and championing performance of the organization's compliance assurance and continuous improvement efforts.
- Through broad awareness of safety issues and performance across the organization, identifying and reporting to management areas of weakness or systemic problems not otherwise recognized by the organization.
- Ensuring contractor managers are adequately trained in the elements of the Price-Anderson program.
- Monitoring contractor compliance assurance program effectiveness and progress in moving to an assessment-driven, continuous improvement-focused organization.

- Managing or overseeing screening of problems, issues, findings, and conditions to identify noncompliances.
- Ensuring that a broad set of issues are screened from a variety of sources, e.g., events, performance assessment reports, nonconformance reports, radiological assessment reports, in a timely manner for PAAA applicability.
- Being knowledgeable of reporting thresholds and having sensitivity for programmatic issues, negative trends, and repetitive issues.
- Performing or ensuring assessments are regularly conducted to evaluate implementation of the contractor's PAAA program and processes.
- Ensuring proper and timely reporting of noncompliances into NTS and local tracking systems.
- Ensuring validation of corrective actions prior to closure, including that corrective actions address the causes, are comprehensive, and have been completed; and marking NTS reports as "complete" only when all actions have been validated.
- Ensuring comprehensive effectiveness reviews are conducted for NTS issues when corrective actions have been completed.
- Facilitating coordination and scheduling within the contractor organization of responses to OE requests for information, onsite investigations, enforcement conferences, focused inspections, and investigations.
- Actively participating in the dialogue between DOE and the contractor in any investigation, focused inspection, or compliance review to ensure the facts and technical issues surrounding the noncompliance are understood, and the actual or potential adverse impact on safety is properly considered.
- Regularly informing senior management of compliance issues, safety performance issues, enforcement actions elsewhere in the DOE complex, and status of the PAAA program.

IV. Compliance Assurance and Reporting

Contractor Compliance Assurance

DOE's safety rules for nuclear and worker safety have been structured to place responsibility for safety and compliance on DOE contractors. DOE's enforcement policies have used the terminology of "compliance assurance" to collectively refer to the set of actions that a contractor should be taking to ensure that it is operating DOE's facilities in a manner that is in compliance with safety requirements.

When OE reviews or investigates noncompliance conditions, OE often notes breakdowns in the contractor's processes to ensure that it was in compliance with the requirements. OE typically notes these deficiencies in an NOV, enforcement action transmittal letter, enforcement letter, or program review report.

To aid in effectively implementing DOE's safety rules, the following are key attributes of top industry performers for assuring that their operations are safe and in compliance with governing safety requirements:

- Key senior managers are designated who are responsible for the major safety programs, and are given the authority to set institutional requirements and provide oversight of implementation. Such program areas under DOE's safety rules include: quality assurance, radiological protection, worker safety, and safety basis.
- A principal regulatory compliance officer is established to serve as the institutional expert and interface on regulatory matters. For DOE safety rules, this is typically the PAAA coordinator.
- Comprehensive steps are taken to ensure that the rule requirements are fully understood, and the requirements are effectively implemented down to the facility level, process, and activity.
- Sound program plans are established to develop the policy-level requirements for the program within that contractor organization.
- A strong focus toward continuous improvement, including benchmarking against other contractors, and adopting best practices to improve safety and compliance.
- Comprehensive management and independent assessments are conducted that effectively identify safety deficiencies and broader programmatic problems in the safety programs, as well as opportunities for continuous improvement by the organization.
- Critiques of performance and safety by outside parties and peers are actively solicited.
- Rigorous problem resolution processes are instituted that manage issue prioritization, assign responsibility, evaluate and determine causes, identify adverse trends and dominant safety issues, determine extent of condition, develop corrective actions, track completion of corrective actions, and review the effectiveness of actions taken.
- Performance metrics are established to monitor safety performance and safety compliance, care is taken to assure that statistics are used appropriately, and that safety incident

reporting is encouraged and incentivized.

In addition to the above, critical roles and responsibilities that are crucial to accomplishing compliance assurance and sound safety performance are summarized in chapter III.

Nuclear Safety Excellence

The objective of DOE's safety regulations is to ensure the safety of the workforce at DOE facilities and the public in the communities that are adjacent to DOE sites. The regulations establish requirements on safety objectives and process controls that if performed well would result in excellence in safety performance. Minimum efforts to comply may keep performance generally acceptable in many instances, but will also have a higher frequency of noncompliance conditions, occasional close-call safety events, and potentially more serious events.

OE would prefer contractors achieve excellence in safety such that enforcement actions are not required. OE has developed a Nuclear Safety Excellence model that captures the key attributes critical to achieving excellence in nuclear safety performance. Material related to the Nuclear Safety Excellence model has been distributed at recent OE workshops and industry meetings. That material will be placed on the OE website.

The Nuclear Safety Excellence model attributes include many of the key attributes listed above in the contractor compliance assurance discussion. OE plans to expand the Nuclear Safety Excellence model to incorporate similar attributes for excellence in worker safety & health, and will similarly place that material on the OE website.

In brief, the Nuclear Safety Excellence model calls for contractors to have no serious nuclear safety events, rare occurrences of other important safety events, a strong assessment driven approach to identifying weaknesses and problems, strong management processes for planning and conducting work and analyzing and correcting problems, and a high degree of compliance with quality assurance, radiological protection and safety basis requirements.

Contractor Screening Processes

While it is the goal that DOE safety requirements are implemented correctly with no noncompliance conditions, it is important to focus on activities to identify and correct any noncompliances that occur to ensure continuous improvement. As noted in chapter II, DOE has adopted an enforcement philosophy that provides positive incentives for contractors to critically self-assess activities, and identify, report, and comprehensively correct noncompliance conditions in a timely manner.

The process of screening problems and deficiencies to determine whether those issues represent noncompliance conditions and the reporting of these into the Noncompliance Tracking System is voluntary on the part of the contractor. The positive incentives for such action are described in more detail in subsequent chapters of this Program Plan. In brief, prompt contractor identification, reporting, and effective correction of safety noncompliances provides DOE with a basis to exercise enforcement discretion in most cases and not take enforcement action, and to mitigate civil penalties when enforcement action is taken. The following describes the desired attributes of the contractor screening and reporting processes.

Noncompliance Identification

It is preferred that rigorous assessment processes, effective trending and evaluation of historical data, worker and management attentiveness, and a questioning attitude will be the primary means of identifying safety and quality problems, some of which will represent noncompliance conditions. By timely identification, DOE means that these issues should be discovered through such proactive means shortly after they occur. If safety issues are not found in a timely manner, the goal and expectation should be that a problem is found through an assessment activity or by worker attentiveness before it results in an adverse event. Obviously, the least desired case would be for a problem to be disclosed through an investigation or evaluation following an adverse safety event. When safety events occur, OE's expectation is that through contractor investigation, causal analysis, extent of condition review, and aggressive corrective action will be undertaken in an expeditious manner such that recurrence of the event is precluded.

Thus, contractor efforts need to first focus on comprehensive implementation of requirements, effective assessment processes, and establishment of the desired safety culture in which individuals can raise questions and report potential problems to management without fear of harassment, intimidation, or retaliation.

Methods of identifying problems include, but are not limited to, the following:

- Contractor assessments - problems may be identified during the course of contractor internal management or independent assessments.
- Internal review processes, such as receipt inspection, maintenance and surveillance activities, and vendor surveillances.
- Worker identified - an organization with a proper compliance and safety-conscious environment will find that workers, in the course of performing their duties, will discover situations that represent abnormal conditions or potential deficiencies. These should be reported to management and entered into the appropriate problem resolution process.
- External assessments - problems may also be identified during the course of external assessments, surveillances, inspections, and visits conducted by DOE Headquarters Oversight, Field, Site, or Operations Office personnel; Defense Nuclear Facility Safety Board (DNFSB) representatives; or employees of a state or the Federal government such as the Environmental Protection Agency, Department of Transportation, or Occupational Safety and Health Administration (OSHA). There should be a minimal number of problems identified through this mechanism if a contractor has an effective assessment program. The goal should be that outside organizations never reveal a significant safety issue that the contractor organization does not already know and is not already addressing.
- Trending and evaluation of operational data and issues management databases to identify adverse trends, dominant problem areas, and potential repetitive events or conditions.
- An additional source for the identification of safety problems may be concerns reported into an established employee concerns program.
- Event related - another means of problem identification is in the evaluation of an undesirable event, such as Occurrence

Reporting and Processing System (ORPS) events. Of prime importance are the underlying problems that led or contributed to the incident. As noted, this is the least desirable method of identifying problems.

Safety and quality assurance problems found by way of the above processes should be placed in an appropriate problem resolution process. Such processes are relied upon to effectively correct identified problems.

Deficiency Screening for Noncompliance Identification

The problem identification processes noted above include problems that can range from serious events with corresponding underlying programmatic problems and safety noncompliances, to relatively minor issues that may need attention but do not represent noncompliances. In order to determine those problems that are noncompliances with DOE safety requirements and to consider those for appropriate reporting, contractors need to implement effective processes to screen problems found by any of the mechanisms described above. Such screening processes should be under the purview of the contractor's PAAA coordinator, governed by one or more formal procedures, and receive input from a broad range of noncompliance identification mechanisms. Sources of issues to be screened for nuclear and worker safety noncompliances should typically include:

- Internal management and independent assessment findings.
- External assessment findings.
- Internal issues management or deficiency reporting system.
- Nonconformance reports.
- Radiological event or radiological deficiency reports.
- Injury reports.
- Computerized Accident Incident Reporting System (CAIRS).
- OSHA 300 logs.
- ORPS reports.
- Operating logs (for issues involved in non-ORPS events).
- Employee concerns.
- Subcontractor deficiency resolution processes analogous to the above.

Observed Screening Process Weaknesses

In conducting program reviews over the initial ten-plus years of the enforcement process, OE has observed a number of common weaknesses or errors in processes for screening deficiencies for potential noncompliance conditions. These are covered here for the purpose of lessons learned by contractors in evaluating their own processes. However, processes should be structured to meet all of the objectives and guidance in this chapter, and not focus solely on the common weaknesses. In summary, these common weaknesses or errors have included:

- Failure to consider all appropriate sources for screening, such as assessment reports, etc.
- Screening out issues as a noncompliance because they were promptly corrected.
- Screening out issues that are noncompliance with rule requirements, but are judged to be of low safety significance.
- Establishing criteria not stipulated in the rules to limit

applicability of the rule, such as only matters covered specifically in the safety basis, or only violations of work controls if the work involved direct-handling of nuclear material, or only violations of procedures specifically listed in rule-required program plans.

Further examples and a more complete identification of the weaknesses noted in screening processes are contained in each of the program review reports listed on the OE website.

NTS Reporting

OE has been granted discretion in pursuing enforcement for many conditions that are contractor identified, receive timely and effective corrective actions, and are properly reported to DOE. To implement that authority, OE has established a process for reporting directly to DOE noncompliance conditions that are potentially more significant, and thus have been selected by OE to receive closer regulator monitoring by OE and DOE and contractor coordinators. These potentially more significant conditions include certain events listed in ORPS as well as other management issues. This process for reporting directly to DOE is the NTS, and is described further below. Matters not meeting the NTS reporting thresholds are to be reported into a contractor's internal issues tracking system and trending to identify potential recurring or programmatic issues, as described herein.

Reporting Thresholds

DOE has established reporting thresholds for reporting noncompliances into the NTS. The NTS is a centralized, web-based system that allows contractors to promptly report noncompliances meeting DOE's established reporting thresholds. NTS also provides on-line "Help" to guide and train users in use of the system. Contractor employee access to the NTS is initially approved by the contractor's PAAA coordinator. Formal authorization to access the NTS is provided by DOE and is obtained in accordance with information at the following web address:

NTS User Authorization Information:
http://www.eh.doe.gov/enforce/nts.html

OE will periodically take steps to improve interfaces between the NTS and other DOE data reporting processes for sharing of common data, where possible. Changes or improvements in this area are addressed on the NTS webpage and through the system's on-line "Help" functions. The NTS web page is located at: https://nts.eh.doe.gov.

OE encourages contractors to use the NTS for the timely reporting of NTS-reportable noncompliances, and to include concise and factual information. For enforcement purposes, prompt reporting is generally considered to be within 20 calendar days after determining that a noncompliance exists.

To obtain consideration for enforcement discretion as well as mitigation based on prompt reporting, the contractor should report noncompliances into the NTS in accordance with the reporting thresholds in appendices A and B, and enter noncompliances that are below the NTS reporting thresholds into the contractor's internal tracking system. Guidance on the attributes of the contractor's internal tracking system is provided later in this chapter.

Although NTS reports are most typically entered by contractor personnel, DOE PAAA coordinators may also submit an NTS report if a contractor declines to do so. However, the preferred approach is to first discuss the matter with the contractor and attempt to convince the contractor that the matter is reportable into NTS.

ORPS Occurrence Associated with a Noncompliance

OE has identified a number of events that have potential significant safety implications. OE is interested in the reporting of safety noncompliances where those noncompliances are associated with one of these potentially significant safety events. A contractor is expected to report into NTS the noncompliances associated with an event or condition that meets any of the ORPS criteria listed in appendix A, table A-1, or appendix B, table B-1, as further explained by the corresponding notes. Appendix A pertains to nuclear safety noncompliances, and appendix B to worker safety noncompliances.

Noncompliances "associated with" means the noncompliance(s) caused or contributed to an event or condition, or occurred concurrently with an event or condition.

Reporting a Programmatic or Repetitive Noncompliance

DOE also is interested in the reporting of programmatic or repetitive noncompliances, as noted in appendix A, table A-1 and appendix B, table B-1. A programmatic problem is typically discovered through a review of multiple events or conditions with a common cause, but may also be found through casual analysis of a single event. A programmatic problem generally involves some weakness in administrative or management controls, or their implementation, to such a degree that a broader management or process control problem exists. When management determines that a problem or series of events or conditions dictate the need for broad corrective actions to improve management or process controls, management has concluded that the problem is programmatic.

Repetitive problems involve generally two different events that involve substantially similar conditions, locations, equipment, or individuals. These generally are narrower in scope than a programmatic problem, and reasonably should have been prevented by a contractor's corrective actions for a previous noncompliance condition involving similar circumstances and root causes. The relative time frames in which the events occurred sometimes dictate a conclusion with regard to whether repetitive issues are involved.

Consideration of programmatic or repetitive problems should not originate due to NTS reporting requirements. DOE expects that normal safety management and quality improvement processes would dictate that when a problem arises, consideration is given as to whether the problem is broader than or a repeat from a prior occurrence. Further, assessment and trending activities should be looking for potential programmatic and repetitive problems. Additionally, PAAA coordinator reviews may provide another avenue for identification of programmatic and repetitive noncompliance conditions through reviews of their noncompliance databases. Programmatic or repetitive deficiencies identified through such processes would normally be placed in a corrective action management process, and then go through the noncompliance screening process to identify any noncompliances. If the identified programmatic or repetitive deficiency involves a safety noncompliance, it should be reported

into the NTS. Such reporting does not necessarily indicate any conclusion regarding the safety significance of the particular noncompliance condition(s) on the part of the contractor making the report.

Reporting an Intentional Noncompliance or Misrepresentation

OE is also interested in the reporting into NTS of an intentional noncompliance with safety rules, as noted in appendix A, table A-2, and appendix B, table B-2. An intentional noncompliance may involve a case in which records are falsified intentionally, such as indicating that a work activity or inspection occurred in circumstances in which the worker knows that such an activity did not occur. In these cases, in addition to any other noncompliance issues that may be present, noncompliance with Part 820.11 regarding accuracy of information may also be involved. The determination of a false record, based on additional evidence that the work did not occur, provides the basis for classifying the condition as an Intentional Noncompliance or Misrepresentation, and, thus, should be reported into the NTS. That is because, irrespective of the significance of the activity involving a false record, the act of falsifying the record and providing inaccurate information is serious, and thus warrants DOE and contactor management attention, including the process of making an NTS report.

An intentional noncompliance can also include a case in which a worker is warned by a co-worker that a certain contemplated action would violate requirements, and then the worker proceeds to take the action anyway. The co-worker's reporting of the incident becomes the evidence that the noncompliance was intentional. Such individual instances of intentional noncompliance should be reported into the NTS. OE must then determine whether the matter should result in an enforcement action.

OE expects that, as in the above examples, where evidence is available that demonstrates that the noncompliance was intentional, the matter should be treated as an intentional noncompliance and reported into the NTS. On the other hand, care must be taken before a conclusion is reached that a noncompliance is intentional. For example, a situation in which a worker was trained to do a certain action and then subsequently failed to do so, may have been a lapse in recalling the training or, possibly, inadequate training, rather than an intentional disregard of the requirements. Without further evidence, there is no basis upon which to report the noncompliance as intentional.

NTS Report Content and Closure

DOE understands and accepts that the initial description of a noncompliance may be limited. Full investigation into a noncompliance and a causal analysis by the contractor is not required before a noncompliance is reported to DOE. Nor will DOE normally pursue an enforcement action based solely upon the initial description of a noncompliance.

As additional information becomes available, OE expects that the NTS report will be updated. In general, the NTS report should include a summary of the noncompliances that occurred. Contractors should provide appropriate information in an NTS report so that DOE understands the circumstances of the noncompliance. The NTS report does not need to repeat or restate the facts and circumstances of the occurrence if there is a corresponding ORPS report. The NTS reference to the ORPS

report is sufficient to allow NTS readers to obtain further details on the event itself. The NTS report may need to provide more information specifically related to the noncompliance(s) than is covered in the ORPS report. The NTS system may be viewed to see examples of the level of detail being used by contractors for NTS reports.

DOE expects NTS reports to be submitted without contractors making a detailed evaluation of safety significance, or a prediction of whether OE would pursue an investigation after receiving the report, as a precondition for reporting. Contractors should simply follow the reporting thresholds in appendices A and B. Contractors may include their preliminary assessment of a noncompliance's safety significance in the "Description of Noncompliance Condition" portion of an NTS report.

Contractors are expected to undertake as many corrective actions as needed to resolve a noncompliance and to prevent it from recurring. OE expects the corrective action section of an NTS report to include the principal corrective actions related to the noncompliance. The NTS report should summarize the conclusions from causal analysis and extent of condition reviews.

Once corrective actions have been completed and all completion dates entered into the NTS, the contractor should mark the report "Completed." An NTS report will not be considered for closure by OE until all reported corrective actions have been completed by the contractor and verified by DOE. Once the contractor has indicated that all corrective actions have been completed, it is essential that the cognizant DOE Field Office conduct a verification. The Field Office PAAA coordinator would subsequently enter comments into the applicable NTS report indicating either that the Field Office is satisfied that all corrective actions have been completed, or that it believes a discrepancy exists and recommends further action to OE. After the Field Office indicates that all corrective actions have been completed and appropriately verified, closure of the NTS report can be recommended to the Director by OE staff. An NTS report is officially closed after the OE Director concurs with the staff recommendation to do so and the report has then been marked as such in the NTS.

Contractor Tracking of Non-NTS Reportable Noncompliances

Reporting a noncompliance that is below an NTS reporting threshold into a contractor's tracking system also constitutes formal reporting to DOE for enforcement purposes. DOE's enforcement policies permit OE to exercise discretion and not pursue enforcement action for such items on the basis of their low safety significance, and that contractors are taking timely steps to correct such noncompliance conditions. OE could choose to take some level of action on these issues if, for example, in a program review it is found that the contractor is not taking timely action to correct such issues that are below the NTS reporting threshold.

OE expects noncompliances below the NTS reporting thresholds to be tracked and managed to resolution in a contractor's internal process. Most typically, this would be managed in the contractor's central issues management or corrective action process. It is expected that contractors have procedures in place to track and manage the resolution of deficiencies in such processes.

OE expects that the contractor will make use of such existing

internal tracking processes to capture, track, and trend worker and nuclear safety noncompliance conditions. To serve as an adequate noncompliance reporting process, the internal tracking controls for noncompliances should at least include the following attributes:

- In some form annotates those problems or issues that are noncompliances.
- Indicates how the problem was identified (discovered).
- References the specific rule section violated.
- Ensures proper resolution (development and completion of corrective actions) of the noncompliance.
- Allows the retrieval of the noncompliances for review and trending by the contractor and DOE.
- Is readily accessible by DOE Field and Program Office coordinators, as well as OE staff when onsite.

Additionally, as noted earlier in this chapter, contractor problem resolution processes should provide the means to trend and evaluate data to identify adverse trends, dominant problems, and potential repetitive problems. OE has observed that the better screening and reporting processes include similar provisions for an additional level of trending and evaluation through review of internally tracked noncompliance conditions.

V. OE Reviews and Communications

OE Review of NTS Reports

OE staff, in coordination with DOE PAAA coordinators, routinely reviews noncompliances reported into the NTS. NTS submission does not mean that an enforcement action will be taken. Rather, OE will review and evaluate all available information prior to determining whether a noncompliance has the requisite safety significance to warrant commencing a more comprehensive review.

When a noncompliance is reported into the NTS, the report is assigned to an OE staff member for review. OE's review encompasses:

- A review the facts contained in the NTS report and, possibly, obtaining other information to confirm that a DOE safety requirement has been violated.
- Performing an initial evaluation of the noncompliance's safety significance to determine if a more comprehensive evaluation by OE is warranted.

OE's review regularly involves communication with DOE and contractor. In some cases, the information provided in the NTS is not sufficient to evaluate the significance of the issues. In these cases, additional information is obtained, such as an event critique, causal analysis, or the contractor's investigation or injury report.

After the review has been performed, the staff member will make a recommendation to the Director on whether to simply track the report to closure or to proceed to a more comprehensive review, focused inspection, or investigation. If it is concluded that a more comprehensive review, focused inspection, or investigation is to be performed, the process for such efforts will follow the guidance in chapter VI, *Investigation Process*.

When the review is complete, and if no enforcement action is to be taken, OE will track the NTS report to closure, as noted above. OE staff and the DOE PAAA coordinators may also, from time to time, evaluate contractor nonreportable noncompliance reports. This typically occurs during a program review but may also be initiated by an unexpected decline in NTS reporting by a contractor or an apparent inconsistency between a contractor's ORPS and NTS reports. If enforcement action is to be taken, the process described in chapter VI of this document will be pursued.

OE Review of Other Sources of Noncompliance Information

In addition to reviews of NTS reports, OE regularly monitors other sources of information on safety issues and events, including:

- Individual ORPS reports.
- Formal inspections or assessments by the Office of Independent Oversight and Performance Assurance, or by DOE Field Offices.
- DNFSB reports.
- Areas of concern raised by senior DOE management.
- Information provided by the DOE Office of Hearings and Appeals, or the DOE Office of Inspector General.

- Allegations communicated directly to OE by a contractor or DOE worker.
- Media reports of events, accidents, or injuries.
- Congressional inquiries.
- Information from other agencies, including the Nuclear Regulatory Commission (NRC), Department of Labor, OSHA, or state and local officials.

It is expected that the primary source of initial notification of significant noncompliances will be from contractor and DOE PAAA coordinators, as part of the desired informal communications maintained with OE. But as material comes to OE from these other sources, OE will evaluate the conditions and request additional information from contractor and DOE coordinators as appropriate.

Program Review

OE regularly conducts program reviews of contractor processes for the identification, screening, reporting, and correction of nuclear and worker safety issues described in chapter IV. OE will also regularly review contractors' assessment processes as part of the program reviews. The purpose of these reviews is to ensure that contractors are applying a sound process to identify noncompliances, make proper decisions on reportability, and undertake timely steps to correct noncompliances. With regard to assessment program reviews, OE's focus will be on determining the effectiveness of these programs in identifying safety issues and on specific improvements that have been made by contractor organizations in assessment processes. Additionally, OE may also evaluate, as part of the program review, selected contractor compliance issues in the areas of radiation protection, safety basis, quality assurance, or worker safety.

A program review is conducted on a schedule-permitting basis, i.e., when OE staff are not otherwise engaged in activities associated with enforcement cases. As a consequence, planning and scheduling a program review is typically conducted on a near-term, quarterly basis. No formal schedules are distributed. However, selected contractors are contacted prior to the review in conjunction with a document request. Program selection is based on a number of factors, such as input from Field Office personnel, site NTS reporting history, OE familiarity with the contractor's program, and contractor replacement. On occasion, OE may conduct a program review in conjunction with a noncompliance investigation.

DOE and contractor PAAA coordinators are typically formally notified of planned program reviews approximately four weeks in advance of the review. The OE staff member leading the review will contact the DOE Field Office PAAA coordinator prior to issuing the program review notification; it is this coordinator who acts as OE's liaison to the Field Office and contractor managements and who oversees the arrangements necessary to support the program review. The notification will contain details on participants, scheduling, agenda items, and other logistics. As part of the notification, OE will request specific documentation from the contractor relating to the implementation of its program. Specifics regarding the document submittal will be included in the request; typically the contractor is requested to provide documentation within ten working days. Appendix C includes the standard program review document request that may be tailored based on the specifics of the review.

The program review is generally conducted by two OE

representatives, and is typically two days in duration. OE staff routinely conduct formal entrance and exit meetings with DOE and the contractor as part of the review. Preliminary conclusions on the strengths and weaknesses of the contractor's program are discussed during the exit meeting.

OE staff utilize the review criteria provided in appendix C as guidance for the conduct of the review. The actual scope of the review, though, may be either broader or more limited than that implied by the criteria, depending upon the specifics of the review.

A draft report describing the scope and results of the review is typically sent to the local DOE office for review within approximately one month after the onsite review. This draft is for DOE internal review only and is not shared with the contractor. The final report of the program review and accompanying transmittal letter are typically distributed within one to two weeks following the receipt of DOE comments. Copies of the final report are mailed directly to the contractor and affiliated DOE offices, and all program review reports are posted on the OE web site.

The final report describes both program strengths and weaknesses identified during the review. OE intends that contractors correct the identified weaknesses after appropriate consultation with and approval by local DOE. While such action is not mandatory and typically no response to the report is required, failure to correct identified weaknesses in a PAAA program may result in the inability of the contractor organization to successfully argue for mitigation of any later enforcement action. Contractor program strengths and weaknesses are identified in the report in an effort to promote communication and lessons learned among the contractor community. OE recognizes, nevertheless, that some strengths may be program or site specific. It is, therefore, not intended that all contractor programs necessarily implement actions to address the program strengths described in each report. In selected instances, OE may identify noncompliances not previously recognized or addressed by the contractor though this is not the focus or intent of the program reviews. The contractor will be informed of any identified noncompliances as soon as possible. OE will subsequently consider the need to address such matters in an enforcement action or an enforcement letter.

While the above approach is used for contractor program reviews for major DOE sites, OE also conducts limited, or "desktop," reviews of contractor programs where the scope of DOE operations is relatively smaller. This is performed using an abbreviated document request and without an onsite visit. A sample document request for a desktop review is also included in appendix C.

Enforcement Letter

If OE's review of the various sources of information discussed previously indicates that there is a matter of safety concern, but the decision is made to not pursue an enforcement action, OE may elect to issue an enforcement letter. An enforcement letter is not a formal enforcement action in that it imposes no requirements, enforcement citation, or civil penalty on the contractor. The enforcement letter will usually identify one or more conditions or situations (A) where performance may have been less than desired but not of sufficient safety significance to warrant an enforcement action, and (B) where contractor attention is required to avoid a more serious condition that would result in an enforcement action. Thus, it can serve as a strong

warning on matters that need attention. The enforcement letter may also highlight actions taken by a contractor that were appropriate and contributed to the decision not to take enforcement action. OE coordinates with the DOE PAAA coordinator and his or her management on the message and conclusions in the letter prior to its issuance. The enforcement letter does not require a response to OE. OE relies on the normal interface between the contractor and local DOE Field Office for communications on follow-up and resolution of the matter.

Enforcement Program Information

OE uses a variety of means to disseminate lessons learned and program changes related to noncompliances and DOE enforcement. Beginning in late 2006, OE is considering the issuance of periodic Senior Management Safety Bulletins which would discuss significant safety issues that have been observed in the DOE complex by OE. These bulletins would generally discuss issues that have been observed among multiple contractors and, thus, are deserving of attention by senior contractor and DOE management across the complex.

The major source of information shared by OE is on OE's internet web site. This web site provides information to the Federal and contractor communities and the general public. Relevant Federal regulations, standards, Office of General Counsel interpretations, enforcement actions, enforcement letters, press releases, enforcement guidance, program review letters, annual reports, and coordinator training workshop information are available there. OE routinely updates its web site to support timely communication and to promote lessons learned across the complex. The OE web site was accessed over 110,000 times in 2005, an indication that the site is a vital avenue of communications for the DOE safety program.

OE also shares information on its expectations and enforcement program processes through its annual training workshop for PAAA coordinators. The workshop typically includes a one-day introductory training session for new DOE and contractor coordinators, and a two-day refresher and updating session for experienced PAAA coordinators. The training highlights noncompliance-related actions taken during the prior year, circumstances of the problems, and the bases for OE action, as well as covering the status of ongoing initiatives and changes in the enforcement program.

OE takes advantage of other avenues of communication, including: regular participation in EFCOG senior management meetings and EFCOG PAAA Working Group sessions; periodic teleconferences with DOE PAAA coordinators; providing information on enforcement actions to the DOE Lessons Learned Program, and frequent meetings with contractor and DOE senior managers.

VI. Investigation Process

Investigation Process Overview

The goal of the Enforcement Program is to encourage proactive behavior by DOE contractor organizations to improve safety performance so that enforcement actions are not required. The result of such proactive behavior is that contractors will find and address safety issues before they result in safety events[3], through performance assessments and other similar processes. However, those cases in which the circumstances warrant the consideration of enforcement action, this chapter describes the investigation process utilized by OE. Note that this process has substantial flexibility so the actual steps taken may differ from case to case depending on the circumstances.

The following steps typically occur for a noncompliance that OE decides to investigate:

- Determine if a noncompliance requires an investigation based on a safety significance evaluation or other contributing factors, and obtain the Director's concurrence to undertake an investigation.
- Initiate the investigation activities in a timely manner.
- Conduct an OE-investigation strategy meeting.
- Inform Field Office and Program Office management.
- Provide a formal notification letter to the contractor of the pending investigation, with an information request if such is needed.
- Conduct an on-site investigation of the matter, if needed.
- Prepare an investigation summary report.
- Decide whether to close the case with an enforcement letter or without any further action.
- Conduct, if necessary, an enforcement conference.
- Determine the severity level of the violations, the associated civil penalty or contract fee censure, and application of mitigation factors.

Any resulting enforcement action would be processed using the guidance in chapter VII.

Safety Significance – Investigation Decision

It is OE's practice to select those noncompliances for investigation that exhibit greater safety significance than the general population of reported noncompliances. This judgment on significance considers both the actual safety significance and breakdowns, as well as any potential safety significance. OE will also consider safety significance when determining the sanctions that are to be imposed in an enforcement action.

The following provide several factors that derive from DOE's enforcement policies and are considered by OE in its determination of safety significance.

[3] For this purpose, OE considers a "near miss" to be a safety event, because in such cases, safety breakdowns have already occurred and the absence of an injury is simply fortuitous in most cases.

For nuclear safety noncompliances, the determination of safety significance is based on the "defense-in-depth" approach to nuclear safety embodied in DOE's nuclear safety regulations:

- The extent to which the safety barriers intended to prevent an abnormal or accident condition have been violated, defeated, or not properly established.
- The extent to which mitigating safety features intended to protect workers or the public in an abnormal or accident condition have been violated, defeated, or not properly established.
- The extent or severity, or both, of an actual adverse nuclear safety event or condition or the potential that it could occur.

For worker safety noncompliances, the determination of safety significance is based on established principles for identifying hazards and providing protective measures for those hazards, as embodied in DOE's worker safety regulation:

- The extent or severity, or both, of an injury or illness that actually occurred or the potential that it could occur.
- The extent to which hazards were not adequately identified or evaluated.
- The extent to which protective measures or hazard controls were violated, defeated, or not properly established.

The breakdowns in levels of controls associated with an event or condition, with the actual or potential consequences of the event or condition, establish the relative safety significance. However, various other factors important to safety are also considered. These other factors apply to both nuclear and worker safety areas, and are applied by OE both in the evaluation of cases to be investigated and in considering the enforcement outcome.

Other Factors Important to Safety Significance:

- Management involvement in, awareness of, or contribution to a noncompliance.
- A repetitive or recurring noncompliance.
- Prior notice by DOE of the problem, and inadequate resolution by the contractor.
- Duration of the noncompliance.
- Multiple examples of a noncompliance as opposed to a single occurrence.
- Discovery of the noncompliance by DOE or other external organization.
- Willful noncompliance or falsification of information.
- Prior enforcement actions (related or not related).
- Lack of timely notification to DOE or reporting into the NTS.
- Slow contractor response to investigate or to take appropriate corrective actions or both.
- Poor safety performance history combined with prior enforcement actions.
- Violation of a compliance order.

The presence of one or more of these factors will generally increase the safety significance, and may be of sufficient concern to lead to an investigation when consideration of the basic safety significance alone would not dictate such an outcome. After

giving consideration to these factors and the basic safety significance, OE will then decide whether the matter warrants an investigation. This is usually based on an initial recommendation by OE staff, with the decision to investigate resting with the Director.

Noncompliance Investigation

Planning and Notification

OE generally commences investigation activities as soon as staff schedules permit after receipt of an NTS report or other information source that is judged to have elevated safety significance. However, to conserve investigation resources when a Type A or Type B accident investigation is being conducted, OE will typically postpone its investigation until after the accident investigation report has been issued, relying to the extent possible on facts gathered in the Type A or B investigation report.

An initial step in the investigation activity is to conduct a strategy meeting on the case with the Director, the lead OE staff member assigned to oversee NTS reports from the respective contractor, and other OE personnel and technical advisors assigned to the case. The purpose of this session is to establish the approach OE intends to follow in identifying potential violations, establishing relevant facts and circumstances, determining significance, and deciding the need for an on-site investigation. Results of the strategy meeting are typically discussed only with affected DOE offices.

Following the investigation strategy meeting, OE will first communicate with DOE Field and Program Office managements to notify them of OE's planned investigation. OE will then provide to the contractor a formal notice letter from the Director informing it of OE's plans to conduct an investigation and the areas to be addressed, and reminding the contractor of the cost segregation requirement.[4] The notification letter may also contain a request for information to support the investigation. In some cases, due to the urgency of the situation, OE may forego this normal notification process and require immediate access to contractor facilities. OE is authorized to take such action for worker safety issues as delineated in Part 851.40(a). Also note that for nuclear safety matters, Part 820.8(a) grants DOE broad authority to obtain information or evidence in order to conduct a full and complete investigation, which would include immediate access to facilities if that is required.

Information Request and On-Site Investigation

OE's information request is aimed at obtaining documentation that aids in understanding the facts and circumstances of the noncompliance condition. OE's investigation activities include a comprehensive review of the material submitted by the contractor and usually an on-site investigation. In some cases, OE may determine that it can adequately conduct its investigation activities without a site visit.

If an on-site investigation is to be conducted, OE formally notifies the contractor and associated PAAA coordinators by letter of the need for the investigation and its proposed date. This notification usually occurs in OE's initial correspondence. OE staff subsequently coordinate with the contractor to establish an agenda and a list of individuals to be interviewed. The

[4] Contractors are required to segregate costs in accordance with the provisions of Public Law 100-700, *Major Fraud Act of 1988*.

investigation typically commences with a DOE-only meeting to discuss the OE team's concerns, areas to be pursued, and obtain DOE Field Office management's input on the matters. OE also usually follows that session with an opening conference that includes DOE and contractor personnel to summarize the purpose of the visit, the issues under review, protocols for interactions, and subsequent communications and deliberations. For worker safety issues, OE will offer the contractor workers involved with the noncompliance(s) under investigation, or their representatives the opportunity to attend the entrance conference. During the investigation, OE may interview workers and managers, inspect facilities and work areas, review records, and identify additional documentation required by OE. Contractors are required to provide complete and accurate information to OE in support of the investigation or other inquiries, as stated in Parts 820.11 and 851.40(b).

Both the information request prior to any investigation, as well as any other documents obtained during or subsequent to the on-site visit, are obtained by way of OE's authority as specified above. Obtaining information through an informal, cooperative means is the most efficient process both for OE and the contractor. If a contractor is reluctant to provide any documentation, OE is empowered by Parts 820.8(a) and 851.40(k) to obtain it by more formal methods, including a subpoena, if necessary.

Focused Inspection Activities

Part 851.40 authorizes the Director, and, hence, OE, to conduct inspections to determine contractor compliance with worker safety requirements. It is OE's expectation that contractors will perform regular and effective assessments of their own compliance with worker safety requirements, such that OE does not need to undertake extensive inspection efforts. Management issues, recent serious injuries and accidents, or adverse performance trends may lead OE to conduct additional inspections to focus on specific areas of concern. Focused inspections will normally be limited in scope and duration and will focus on specific areas of concern. OE may choose to conduct focused inspections for any reason, such as for the following:

Observations made during the onsite portion of an investigation may indicate that a potential compliance problem exists in a specific location or functional area (e.g., during a building walkthrough the enforcement specialist notes numerous electrical safety hazards and determines that a focused inspection is needed to evaluate electrical safety issues in the building or facility). Regardless of whether OE observes other conditions during its onsite investigation that would warrant a focused inspection, a focused inspection may be conducted in conjunction with the onsite portion of an investigation in order to use resources wisely.

A review of data suggests a possible negative compliance trend in a specific type of operation, work activity, or functional area (e.g., a trend analysis of NTS or ORPS data suggests an increase in fall related injuries across the Department; as a result, OE determines a series of focused inspections are warranted at selected sites to evaluate compliance with fall protection requirements).

Other indicators or events suggest a need for increased focus or attention at a specific location or in a specific functional area.

If a focused inspection is conducted in conjunction with an investigation, the enforcement specialist will notify the contractor

(as well as the DOE and contractor PAAA coordinators) as soon as practical that the scope of the investigation will or has been expanded to include a focused inspection. This notification will describe the general scope of the focused inspection. If additional subject matter expertise is needed for the focused inspection, OE may schedule a follow-up visit to conduct the focused inspection.

It is OE's intent that the preliminary results of a focused inspection be provided to the contractor at the exit briefing. The closing conference will provide a summary of any noncompliance conditions noted by the team in the focused inspection so these may be addressed in a timely manner by the contractor. OE may decide, if the findings of the focused inspection are generally complete, to consider the exit briefing as an informal enforcement conference. The contractor will be notified by the OE team during the site visit if the closing conference will serve as an informal enforcement conference. However, if OE has notified the contractor prior to the site visit that an investigation is to be performed, the normal process for advance notification and conduct of an informal enforcement conference at OE's office will typically occur if a conference is to be held.

Request for OE Investigation

10 CFR Part 851.40(c) provides a worker or that person's representative the right to request the Director to initiate an investigation or inspection for worker safety issues. Similarly, Part 820.21 provides any person the opportunity to request an investigation or inspection for nuclear safety issues. A worker or worker representative may also submit an anonymous request for an inspection or investigation. Alternatively, the worker or worker representative may submit either a request for inspection or investigation with a request to maintain confidentiality. When requesting confidentiality, the alleger should be aware that although OE will take every precaution to not disclose the individual's identity to a party outside of DOE, in many cases the nature of the issue itself could provide some indication of who is the alleger. The additional restriction of maintaining an alleger's confidentiality may also limit the effectiveness of the OE investigation, in the event OE decides to conduct such an investigation.

Note that Part 851.20(a)(6) requires management to establish procedures for employees to report, without reprisal, job-related fatalities, injuries, illnesses, incidents, and hazards and make recommendations about appropriate ways to control those hazards. In addition, sections 851.20(b)(7), 851.20(b)(8), and 851.20(b)(9) give workers the right, again, without reprisal, to express concerns related to worker safety and health, to decline to perform an assigned task if the task poses an imminent risk of death or serious physical harm, and to stop work if they discover worker exposures to imminently dangerous conditions or other serious hazards.

OE anticipates that prior to requesting an investigation, workers, and worker representatives will exhaust all contractor and local DOE mechanisms to express and resolve worker safety and health concerns associated with compliance with the Part 851 rule, or nuclear safety concerns.

Note that OE is developing a web-based request form to facilitate such requests for investigation, and will place that on the OE website when developed. Until that is available, a request for an investigation should be transmitted to OE via U.S. mail at the following address:

EH-6/270 Corporate Square Building
U.S. Department of Energy
1000 Independence Avenue, SW
Washington, D.C. 20585-0270

The request for investigation should, to the extent possible, include the following information:

- Requestor's name, job title, and contact information (phone number, e-mail address, work address). If the request is made by a worker representative, the request should also describe the nature of the representation (e.g., union, elected representative, attorney) and the name of the worker or workers for whom the request is made.
- Request for confidentiality (if preferred).
- Date of request.
- The DOE site location.
- Employer's name.
- Specific work area where the alleged hazard or potential violation exists.
- Description of the alleged hazard or potential violation, including activities involved, number of workers potentially exposed and for what duration, any previous incidents (e.g., injuries, near misses) involving the hazard, and the requestor's role in the activity. Supporting documentation or information such as internal inspection results, e-mails, written workplace procedures, etc., should also be included.
- Description and results of efforts to resolve the concern through existing contractor and local DOE mechanisms, including formal employee concerns program. Include available documentation of such efforts, if any.
- Signature of the requestor.

If such a request is made to OE, OE will notify the respective Program and Field Office PAAA coordinators, as well as the contractor PAAA coordinator, and, if requested, will honor the requestor's desire for confidentiality. OE will evaluate each request for investigation to determine if an investigation is warranted. If additional information is needed to make this determination, OE will coordinate with the DOE PAAA coordinator and the requestor (where appropriate) to obtain the information needed to make the determination.

For such requests OE will evaluate the conditions in the same manner as any other issue considered for investigation. OE may choose to investigate an issue or alleged condition if it concludes that a significant safety noncompliance may have occurred that potentially warrants enforcement action. The judgment to pursue or not pursue such requests rests solely with OE, and is based on all of the information and evidence available to OE, including that obtained from DOE PAAA coordinators or other sources. If OE decides to undertake such an investigation, it will follow the process described in this chapter.

OE will communicate its decision and the basis of its determination on whether to investigate to the requestor, and the results of any investigation will be documented and processed as described above for OE investigations. The requestor will be notified of the results, either after issuance of a NOV or following the investigation if no enforcement action is to be taken.

If OE receives an anonymous request for investigation, it will proceed as described above. However, OE's efforts are

obviously hampered in not having access to the individual(s) with first-hand knowledge and information of the alleged noncompliance.

Investigation Report/Documentation

In most cases, when investigation activities are completed, the investigation team will document the results. In some cases, the available documentation may be sufficient to support proceeding directly to a PNOV without development by OE of an investigation summary report or other investigation documentation.

When documentation, such as an investigation summary report or focused inspection report, is to be used to document OE conclusions on the noncompliance(s), the documentation typically will include:

- A summary of the facts and circumstances of the noncompliance(s) and associated event(s).
- Specific noncompliance(s) with any regulation(s) that occurred.
- Specific document references or other factual details related to the noncompliances.
- A discussion of safety significance.
- Facts that may be relevant to consideration of enforcement mitigation (and potential escalation, if applicable).

The investigation and documentation will also address the following factors if relevant to the noncompliance(s):

- Duration.
- Management involvement
- Timeliness of reporting
- Causal analysis.
- Extent of condition.
- Assessment deficiencies in failing to discover the problems.
- Recurring events or problems.
- Prior DOE notice.
- Immediate actions.
- Corrective action plans.
- Plans to conduct effectiveness reviews.

If an on-site informal enforcement conference is conducted, a conference summary will be included as part of the enforcement action documentation.

The investigation documentation will include a recommendation to the Director on any subsequent course of action, which could include proceeding to an enforcement conference, proceeding with enforcement action, or not pursuing an enforcement action. If OE is proceeding directly to an enforcement action, that action will be processed as discussed in chapter VII, and the investigation documentation report will be included. The decision to take an enforcement action rests with the Director (or NNSA Administrator for NNSA facilities). If the Director's decision is to conduct an enforcement conference, the contractor is notified by letter and the investigation summary report is enclosed. If the decision is to not proceed with an enforcement action, the case may be closed through the issuance of an enforcement letter (described in chapter V) or by notation in the associated NTS

report(s). In some cases OE could issue the investigation summary report with the issuance of the PNOV. This could happen, for example, in cases in which an enforcement conference has been held at the conclusion of an on-site investigation.

Enforcement Conference

Purpose

An informal enforcement conference may be called at any time at the discretion of the Director. An enforcement conference may be requested by a contractor, but the authority resides with the Director as to whether to conduct such a conference. The primary purpose of an informal enforcement conference is to provide an opportunity for the contractor to address the facts and noncompliances noted by OE in its investigation documentation, and to address steps being taken to resolve the noncompliances and underlying causes. An enforcement conference is held for most enforcement action proceedings, although it is not mandatory and the Director may choose, in certain cases, not to hold a conference. For example, an enforcement conference is generally not held for a nuclear safety issue that is expected to result in a nuclear safety-related severity level III violation.

Scheduling and Notification

In general, if an enforcement conference is planned, it would be held before an NOV is issued. To provide for the timely processing of an enforcement proceeding, the contractor is typically informed of the intent to conduct a conference at least two weeks in advance.

OE will typically notify the contractor by a letter signed by the Director of the enforcement conference date, time, and location. The notification letter will generally include or reference documents covering the facts and circumstances of the noncompliance(s), typically in the form of an investigation summary report or other investigation documentation, OE's conclusions on the noncompliance(s), and any issues that should be discussed by the contractor.

In some cases, OE may hold an enforcement conference on-site at the conclusion of a focused inspection or investigation. In that case, after the Director provides authorization to proceed with the conference and designates the OE staff member who will chair the conference, the OE team will then notify the contractor during the inspection or investigation that an enforcement conference will be held at the completion of the on-site visit. These cases will generally be ones where the facts and circumstances are clear, and any further review of information is not required to identify the noncompliance(s).

In cases where OE has issued the investigation summary report with the PNOV, or otherwise proceeded directly to a PNOV without an investigation summary report or other investigation documentation, OE may still convene an enforcement conference after issuance of the PNOV.

Attendance

DOE personnel, as a minimum, should include the Director or OE staff member who will chair the conference, the responsible OE staff and technical advisors involved in the case, Program Office and Field Office management representatives, and the PAAA coordinators from the Field or Program Office. To achieve the

best prospect of influencing contractor safety performance improvement via the enforcement conference, it is also highly desirable that senior Field Office and Program Office management attend. These individuals will be notified of the conference and, through verbal or e-mail communications, strongly encouraged to attend. Other DOE personnel may attend at the request of and as permitted by the Director.

DOE contractor personnel should, as a minimum, include senior contractor management, e.g., Laboratory Director, President, etc., key management personnel involved in the event or conditions as well as the actions to correct the underlying problems, and the contractor PAAA coordinator. Participation by representatives from the Board of Directors and corporate management of the parent company or governing university is strongly encouraged.

As stated in DOE's enforcement policies[5], enforcement conferences are pre-decisional actions intended to provide a forum for open and candid discussion regarding a potential enforcement issue. Therefore, they are normally closed meetings between DOE and the contractor (but, including the parent organization's management). This excludes the media and public from attendance.

Conduct of Enforcement Conference

In general, conferences are informal and conducted without a transcript of the proceedings in order to encourage candor.

Enforcement conferences are chaired by the Director or OE staff designee. After preliminary opening comments by the Director and the introduction of attendees, the conference is then turned over to the contractor. The conference is primarily the contractor's opportunity to address key factors related to the case. During the conference, all DOE officials are encouraged to pose questions to seek clarification or to ensure that key points are addressed.

The contractor should identify any factual issues related to OE's investigation or inspection report, or other document relied on by OE in identifying noncompliances. Additionally, the contractor should address the causes of the noncompliances, its views of their safety significance, the corrective actions taken to correct the immediate problems and to prevent recurrence, and the application of mitigation and discretion factors.

The level of detail of the contractor's briefing should be related to the complexity and significance of the issues. In general, a summary of the noncompliances, how they were discovered, their causes, and related circumstances is helpful, but need not be detailed. A substantive, thorough discussion of the corrective actions and measures to ensure the violations will not recur is, however, critical. It is also beneficial to demonstrate that representatives from the Board of Directors and corporate management from the parent company or governing university are involved in the oversight of safety performance and ensuring that the violations are corrected. The typical duration of an effective conference is on the order of about two to three hours, but contractors are permitted to take whatever time they need. Any material provided by the contractor at the enforcement conference is placed in the docket file for the case.

[5] *General Statement of DOE Enforcement Policy*, 10 CFR Part 820, appendix A, as amended, for nuclear safety violations, and *General Statement of Enforcement Policy*, 10 CFR Part 851, appendix B, for worker safety violations.

At the conclusion of the contractor's presentation and response to questions from DOE, OE will close the conference and make clear that the final DOE decision on the matters will be made subsequent to the conference and be provided to the contractor at a later date.

Post-Conference DOE-Only Meeting

Following the enforcement conference, and after all the contractor's personnel and representatives have departed, the Director or designee reconvenes the DOE participants for preliminary discussions. The intent is to arrive at a consensus on any facts presented by the contractor, whether an enforcement action should be taken, the violations that occurred, their safety significance and severity level, the application of civil penalties, treatment of mitigation factors, and messages that should be communicated in the transmittal letter for the enforcement action. These discussions represent the preliminary deliberations on any enforcement action.

Enforcement Conference Summary Report

After the enforcement conference, a brief report will be prepared by OE to document the conference discussions. The summary report will typically include the contractor's position on the accuracy of facts in the OE investigation summary or other documents that are the basis for any potential violations, a brief description of significant additions or corrections to the factual information which are the basis for any potential violations, a brief description of any significant additional information which affects the safety significance or mitigation factors, and a summary of the contractor's short-term and long-term corrective actions.

Prior to finalizing the conference summary report, comments and input will be obtained from the DOE Program and Field Offices via the DOE PAAA coordinators. The conference summary report is typically attached to the enforcement action.

Confidentiality of Deliberations

Following the enforcement conference and prior to issuance of the enforcement action, any discussions and deliberations within DOE about the case and possible action by DOE, including the post-conference DOE-only meeting discussions, are confidential. Because these discussions involve a pre-decisional matter by DOE, any information pertaining to that action is not to be communicated to the contractor or members of the public.

VII. Enforcement Action

Possible enforcement actions include notices of violation and compliance orders. Once the circumstances surrounding a noncompliance and its safety significance are understood, and any enforcement conference and preliminary deliberations are completed, it is OE's responsibility to consider the appropriate enforcement action. This chapter describes the process of developing the enforcement action and OE's considerations in that process.

Summary of Enforcement Action Process

The process below summarizes the most typical enforcement process and applies to both nuclear safety and worker safety violations, except where noted.

- OE staff develops a proposed aggregation of violations, specific violations to be cited, appropriate severity levels, corresponding civil penalties, and draft communication to the contractor.
- OE solicits Field and Program Office comments on the proposed action and correspondence, and the Director's approval (Administrator for NNSA facilities).
- DOE issues the preliminary notice of violation (PNOV) or other action.
- The contractor has 30 days to respond in writing and may contest the notice with substantive evidence not previously considered, contest the civil penalty, request additional mitigation, if applicable, or accept the notice and waive the right to contest.
- If the PNOV is uncontested, it automatically becomes a final order.
- If the PNOV is contested, the Director (or NNSA Administrator for NNSA facilities) considers the arguments made and determines the final action. DOE's response to the contractor converts the PNOV to a final notice of violation (FNOV).
- Once an FNOV is issued, 10 CFR Part 820 provides an opportunity to the contractor for an appeal, if desired; this is described further in the Program Plan. If the FNOV is not appealed by the contractor, the FNOV becomes a Final Order.
- In general, all records and correspondence related to a pending enforcement action prior to the issuance of a final order are considered "pre-decisional" and thus are not subject to disclosure under the *Freedom of Information Act*.
- Records related to an enforcement action are placed in the OE docket file.

The Director is authorized to issue PNOVs, FNOVs, final orders and consent orders for non-NNSA facilities, and the NNSA Administrator issues these documents for NNSA facilities based upon the recommendation of the Director. Compliance orders must be executed by the Secretary. Consent and compliance orders follow some of the elements of the above process, but the unique aspects of these type actions are addressed later in this chapter.

Preliminary and Final Notices of Violation

Preparation of Preliminary Notice of Violation

A PNOV is a finding by DOE that, based on the evidence developed in its investigation, a violation of a nuclear safety or worker safety rule has occurred. The PNOV includes the following elements as a minimum:

- A concise, clear statement of the requirement(s) that was violated, (legal citation for the violation).
- A brief statement of the circumstances of the violation, including the date(s) of the violation and the facts to demonstrate that the requirement was not met (e.g., "contrary to" paragraph).
- The severity level proposed for the violation or problem area if violations are classified in the aggregate.
- The civil penalty proposed for each violation, or group of violations, as applicable.

The "contrary to" paragraph should clearly demonstrate how the DOE safety requirement was not met. Specific reference to evidentiary material should be made, such as a reference to a specific procedure or specification that proves the violation. The PNOV also informs the contractor of the response required to be made to DOE.

A group of violations related to the same safety requirement, or related to a singular event may be evaluated in the aggregate. A group of violations that is aggregated will be designated a violation at the appropriate severity level warranted by the facts and circumstances of the specific case. By addressing a group of violations that individually may have minor safety significance, the PNOV can highlight the more significant condition or underlying programmatic problem. Violations, when aggregated in this manner, may have a higher severity level then the individual violations. In addition, the circumstances involving an event and a series of corresponding violations may not warrant citing each of the violations individually and, thus, aggregation of the violations would be used to mitigate the associated civil penalties.

The Director and OE staff will prepare the draft of the enforcement action--PNOV--and conduct any other required internal discussions within DOE before arriving at a position on the required action. Drafts of the PNOV, transmittal letter, and conference summary are provided to Field and Program Office personnel via the DOE PAAA coordinators for review and comment. For NNSA facilities, the proposed action is forwarded with a transmittal memorandum summarizing the basis for the recommended action to the NNSA Administrator for signature.

PNOV Transmittal Letter

The cover letter transmitting the PNOV to the contractor will include sufficient factual information described in "executive summary" format to permit contractor management to understand DOE's safety and management concerns, how DOE determined the sanctions that it is proposing, and where DOE concludes the contractor should focus its attention to improve its performance. The letter will be specific enough that the contractor receives a clear message as to how the DOE enforcement staff has applied the enforcement policy, and clearly identify contractor actions that reflect good performance and areas that require additional attention. The letter will include the following elements, as appropriate:

- When and where an inspection, investigation, or assessment was conducted.
- Who identified the violation(s), i.e., the contractor, DOE, or other external source.
- If and how the violation was reported.
- When and where an enforcement conference was conducted and reference to any conference report.
- A summary of the violations, severity level, and any other major attributes of the violations related to safety significance of the violations.
- Identification of any factors that affected the escalation or decrease of the action, such as repetitive nature of the event, extended duration of violations, management deficiencies, or willfulness.
- Discussion of application of mitigation factors.
- Identification of resulting proposed civil penalty
- A description of the response that is necessary from the contractor and the time within which it is expected to be received.
- A statement that DOE will determine what, if any, further enforcement action is required after review of the contractor's response to the PNOV, proposed corrective action, and results of future assessments.

Contractor Response to PNOV

A contractor is required to respond to the PNOV either by accepting its conclusions or by presenting additional evidence that was not previously presented in the investigation and that could lead to an outcome different from the one set forth in the notice. The transmittal letter typically informs the contractor of options to: 1) admit or deny the alleged violations, (2) identify any facts set forth which are asserted to be incorrect, and (3) provide the reasons for the violations if admitted, or if denied, the basis for the denial. The contractor is also asked to delineate in the NTS, with target and completion dates, the corrective actions that have been or will be taken to avoid further violations.

The contractor's response is due within 30 days of the PNOV's date of issuance. The Director, OE staff, and responsible Field and Program Office personnel carefully review the contractor's response. Where additional information is provided, OE will consider whether the action should be modified.

If the contractor admits that the violation(s) occurred as described in the PNOV, and pays the civil penalty (in a case involving a civil penalty), OE will send the contractor a letter that acknowledges receipt of the monetary penalty (for a case with a civil penalty) and deem the PNOV to be final order. Acknowledgment letters are generally issued within 30 days after receipt of the contractor's response to the PNOV.

The contractor has the option to challenge DOE's facts, the determination of violations, conclusions on safety significance or severity level, application of mitigation factors, or other elements regarding the PNOV. Following a review, the Director may conclude that it is appropriate to move to an FNOV.

Final Notice of Violation

As noted above, if the contractor admits the violation(s) as addressed in the PNOV and pays any associated civil penalty,

the PNOV automatically becomes a final order, thus eliminating the need for an FNOV.

If the contractor challenges any aspect of the PNOV, the challenge is carefully reviewed by OE in conjunction with DOE Field and Program Office management. Upon evaluation of contractor responses and all other relevant evidence, the Director may take one of the following actions as deemed appropriate:

- Rescind all, or part, of the proposed civil penalty.
- Rescind all, or part, of the PNOV.
- Issue the FNOV and impose a civil penalty, as authorized by law, in cases where the PNOV is not fully rescinded.

The FNOV will generally follow the same format and content as the PNOV, but will be updated based on any new information to reflect DOE's final conclusions on the matter. The Director is authorized to issue FNOVs for non-NNSA facilities, and the Administrator, NNSA, for NNSA facilities.

A nuclear safety FNOV without a civil penalty becomes a final order 15 days after service, unless it is modified by an order from the Secretary of Energy. All worker safety FNOVs, and nuclear safety FNOVs with a civil penalty, become a final order if the contractor does not contest the FNOV within 30 days, pays any civil penalty, and complies with the other requirements set forth in the FNOV.

Processes to appeal an FNOV are established in Part 820, subpart B, for nuclear safety FNOV's with a civil penalty, and Part 851.44 for worker safety FNOV's. In brief, these are:

- For worker safety FNOVs, the contractor may appeal within 30 days to the DOE Office of Hearings and Appeals, following the process in 10 CFR Part 1003, subpart G.
- For nuclear safety FNOVs with a civil penalty, the contractor may request an on-the-record adjudication. Alternatively, an appeal action can be commenced in Federal District Court.

These appeal processes are set forth in the above-referenced regulations, and will not be discussed further in this Program Plan. The processes followed by OE are extensive in ensuring the completeness of the information provided by the investigation team, the accuracy of documentation referenced, and the correctness of the violations cited. Contractors have substantial opportunity to provide input during the process and feedback on factual accuracy. Accordingly, the need for a contractor appeal is rare.

Severity Level

OE reviews each case being considered for enforcement action on its own merits to ensure that the severity of a violation is characterized at the level best suited to the significance of the particular violation. In some cases, special circumstances may warrant an adjustment to the severity level categorization.

Guidance was provided in chapter VI on the determination of safety significance, including other factors that affect safety significance. Guidance on the classification of safety violations is provided in DOE's enforcement policies as follows:

- For nuclear safety violations, section VI of the *General Statement of Enforcement Policy*, appendix A to Part 820. Violations are classified as severity level I, II or III.

- For worker safety violations, section VI of the *General Statement of Enforcement Policy*, appendix B to Part 851. Violations are classified as severity level I or II.

The definitions in these enforcement policies are used as a starting point by DOE reviewers on a recommended severity level. Note that in considering the severity level, the reviewer will consider both the actual as well as the potential consequence (safety significance) of the violations. The severity level may be adjusted up or down by DOE based on the circumstances of the particular violation. The following summarize the general treatment by OE of some of the more common factors that affect adjustment of severity level.

Aggregation of Violations

When several violations are evaluated in the aggregate, indicating a broader underlying problem, the underlying problem is generally assigned a higher severity level than that which the individual examples may have deserved. The resulting classification may be referred to as a "Severity Level (specify) problem" versus using the terminology Severity Level (specify) violation.

Severity Level Escalation

For nuclear safety violations, DOE's enforcement policy establishes specific considerations that may raise the severity level of a violation even in the absence of a significant radiological risk. These include the following:

- Position, training, and level of the individual involved in the violation. Management involvement is generally dealt with more severely by DOE, particularly if senior management is involved.
- Prior notice of the problem. If such notice was clearly given, whether internal, such as an internal assessment, or external, such as by DOE, failure to adequately correct the problem results in a more significant action.
- Duration of a violation. If the matter existed for some time, and was clearly identifiable such as by assessment activities, tests, or inspections, or direct observation by workers or management in the course of conducting work activities or facility surveys, OE generally classifies the condition at a higher level.
- Past performance of the DOE contractor in the particular activity area involved.
- Multiple or recurrent examples of a violation.

OE considers these aspects in each case, and to the extent these were present will address then in its investigation report. Additionally, these areas of concern will be emphasized in the enforcement action transmittal letter.

For worker safety violations, these factors are not used to determine severity level, however, they may be considered as adjustments to the base civil penalty.

Civil Penalty Factors not Affecting Severity Level

DOE's enforcement policies establish various factors to be considered that may affect mitigation or escalation of the civil penalty. These factors are not generally considered in determination of the severity level to avoid a double-hit for those

factors. These factors include adequacy of identification of the violation, reporting, casual analysis, and corrective actions. See the *Adjustment of Base Civil Penalty* section for additional information.

Low Significance Violations

DOE's enforcement policies provide that NOVs need not be issued for noncompliance items which are minor variances with safety requirements. Part 851, appendix B, section VI, refers to such conditions as "de minimis violations." Such discretion is exercised so DOE can focus its enforcement activities on matters that have greater actual or potential significant impact on worker and nuclear safety. Noncompliances that do not result in an NOV should still receive appropriate contractor attention to ensure they are adequately corrected, and should be properly tracked and evaluated to identify repetitive conditions or to assess generic or facility-specific problems.

For nuclear safety noncompliances, severity level III violations should be reserved for selective less significant conditions to stimulate contractor attention to address these before they result in a more significant condition. Both for worker and nuclear safety conditions, OE may also use an enforcement letter to direct contractor attention to resolving such precursor conditions.

DOE may refrain from issuing a PNOV for severity level III violations if (A) the contractor timely identifies and reports a noncompliance condition, (B) DOE is satisfied with the causal analysis and corrective actions, and (C) the matter does not appear to be of a recurring nature.

Base Civil Penalty

Both the worker safety (Part 851, appendix B) and nuclear safety (Part 820, appendix A) enforcement policies state that civil penalties are designed to emphasize the importance of compliance and to deter future violations, as well as to encourage early identification and reporting of violations, and their prompt correction. Furthermore, the overall outcome of the enforcement action developed by OE, including the magnitude of the civil penalty, generally takes into account the gravity, circumstances, and extent of the conditions surrounding the violation. As such, OE may propose to group certain violations that are related, or may choose to cite the violations separately, in order that the resulting enforcement outcome is commensurate with the significance of the case.

Civil penalties are not typically be proposed for nuclear safety severity level III violations as described in the previous section. However, there are circumstances where a civil penalty may be appropriate in order to emphasize the importance of adherence to DOE's nuclear safety requirements, or where the violation(s) are similar to previous violations for which the contractor had not taken effective corrective action.

Once OE has established the specific violation(s) that are to be cited, including any violations that have been grouped, and their applicable severity level(s), the base civil penalty is then established for each using the tables in the DOE enforcement policies.

Adjustment of Base Civil Penalty

After the appropriate base civil penalty is determined for a case,

the civil penalty adjustment factors outlined in the enforcement policies are used to determine the magnitude of the civil monetary penalty that is to be assessed.

DOE provides substantial incentive for the early self-identification and reporting (up to 50 percent mitigation). Substantial mitigation (up to an additional 50 percent mitigation) is also possible if corrective action is prompt and aggressive. Accordingly, DOE will apply a number of factors in assessing each potential enforcement situation. In determining whether an enforcement action will be mitigated, DOE will consider, among other factors, the opportunity available to discover the violation, the ease of discovery, the promptness and completeness of the notification report to DOE, and the scope and promptness of the corrective actions.

Mitigation for Identification and Reporting

Reduction of up to 50 percent of the base civil penalty may be given if the DOE contractor identified the violation and promptly reported the violation to DOE. In weighing this factor, consideration will be given to, among other things, whether the problem was disclosed through an event; whether prior opportunities existed to discover the violation, and if so, the age and number of such opportunities; prior knowledge of the violation; the extent to which proper contractor controls should have identified the violation; whether discovery of the violation resulted from a contractor assessment activity or was discovered by an external body such as DOE; and the promptness and completeness of any noncompliance report.

Timely self-identification means identifying a nuclear safety problem before it leads to an incident with undesirable consequences. The contractor's focus should be on performance assessment or other means and processes to identify such problems, rather than being forced to react to an event. Hence, if identification of a noncompliance is the result of contractor initiative or through a contractor's efforts to understand the broader implications of a particular noncompliance condition or incident, DOE would generally grant mitigation for self-identification, assuming proper reporting occurred. However, where an event discloses the existence of a problem, and the underlying noncompliances are identified only as a consequence of routine review of the incident, DOE would likely not consider mitigation for self-identification, even if eventually reported by the contractor. This is referred to in the enforcement policies as a "self-disclosing" event. DOE's desire is for contractor initiative to identify such problems before they lead to events with actual or potential safety consequences, primarily through excellence in performance assessment programs.

Mitigation for Corrective Actions

Prompt, comprehensive, and effective corrective actions for safety violations are desired by DOE. Mitigation of up to 50 percent of the base civil penalty may be provided if these factors are present. In applying this factor, OE considers (depending on the circumstances) the timeliness of the actions, the contractor's initiative to take action, the rigor with which the contractor identifies the cause(s), adequacy of extent of condition reviews, whether this is a repetitive problem or occurrence such that prior corrective actions were not effective, and the comprehensiveness of the corrective actions.

The following are particular circumstances or factors considered by OE in application of its authority to provide mitigation and to

provide positive incentives for desired contractor actions:

- OE will normally not give credit for a contractor's corrective actions if DOE intervention was required to broaden the scope or increase the extent of the corrective action.
- Mitigation is also not appropriate merely because immediate remedial actions are taken to correct a condition, but broader corrective actions to prevent recurrence must be present.
- As part of the corrective action effort, adequate and timely causal determination, extent of condition review, and corrective action development must occur. OE has established a guideline that it uses in judging timeliness in this area, and it is that most investigations, causal analyses, and development of corrective actions should typically be completed within 45 days of determining that a noncompliance exists. OE also recognizes that in some cases involving significant events with deficiencies that are broad in scope, it may take longer than the recommended 45 days to complete the above. Contractor failures associated with timely and adequate analysis and corrective action development could lead to full or partial reduction in the allowed mitigation.
- The judgment on adequacy of corrective actions is based on whether the actions appear sufficiently comprehensive to correct the noncompliance and prevent recurrence. OE solicits DOE Field and Program Office input on this judgment.
- Due to the time required to form a basis for a judgment on effectiveness and the need for a timely enforcement action, data on effectiveness of corrective actions may not be available. However, if available it will be considered by OE in its judgment on corrective action mitigation.
- If the violation or event under consideration is concluded to be one that had a precursor event for which the underlying problems should have been recognized and corrected earlier, or there is a recurring problem, OE will not normally provide full mitigation for corrective actions. These conditions indicate that prior corrective actions were not effective and were not timely. However, comprehensive action once the problem is finally recognized could be considered by OE for partial mitigation. Critical to this judgment will generally be the egregiousness of the failure to previously correct the problem, its duration, the seriousness of the subsequent event, and the degree of DOE involvement in effecting the proper attention.
- Both DOE's worker safety and nuclear safety enforcement policies permit increase of the base civil penalty if corrective actions are substantially inappropriate. For example, if substantial effort is required by DOE to convince the contractor to take corrective action, or if the contractor's corrective action is considered untimely and inadequate due to the contractor's failure to fully recognize or understand the extent of the problem, OE may consider escalating the civil penalty above the base amount.

Appendix F provides information on common breakdowns and weaknesses in the contractor investigation, causal analysis, and corrective action area that have been observed by OE. These should serve as lessons learned for contractors to consider as they assess and strive to improve their own processes.

Application of "Per-Day" Provisions

The PAAA and the 2003 Defense Authorization Act each authorize a statutory maximum civil penalty ($110,000 for nuclear safety and $70,000 for worker safety) per violation per day. Thus

a noncompliance condition that exists for several days could result in an enforcement action with a base civil penalty substantially above the base per-day amount. OE's policy is to generally use the base single-day amount as the starting point for most violations, and to consider multiples of that value by applying the per-day provisions only for the most significant long-standing or recurring problems. In this regard, contractors have been on notice for some time that recurring violations will be dealt with severely in the enforcement process.

A per-day calculation of a civil penalty will normally be considered when the significance of the violation is such that use of a single-day base civil penalty is not sufficient to convey the seriousness of the violation or circumstances leading to the violations, the violations existed for a longer duration than a single day, and substantial opportunities existed to identify the violations. Examples of substantial opportunity to identify the violation include the following: (A) management was aware of the violation and chose not to take appropriate action to remedy the problem, or (B) the violation existed for an extended period and substantial opportunity existed to identify the problem through proper assessment or evaluation activities.

The number of days considered by OE to be appropriate for citation in such cases will be such that the resulting action is consistent with the seriousness of the violations and their resulting actual or potential consequence.

Multiple Separate Violations

The *Severity Level* section noted that OE could aggregate individual violations into a single "problem" and cite that problem at a higher severity level. Additionally, OE can separately cite multiple violations and impose civil penalties for each of the multiple violations in a citation. Each violation is subject to the statutory per-day limit. This means, for example, that a single event involving violations of worker safety, radiological protection, and quality assurance requirements could result in a PNOV individually citing these violations and imposing a civil penalty associated with each.

The significance of a particular occurrence and the circumstances of the violations may dictate that DOE identify the multiple violations involved and impose civil penalties for each to communicate the right emphasis on the significance of the violations and the attention that is required by the contractor to correct the conditions that led to the violations.

Exercise of Discretion

Because DOE wants to encourage and support contractor initiative for prompt self-identification, reporting, and correction of problems, DOE's enforcement policies grant OE broad discretionary authority to recognize positive steps by contractors. That discretionary authority can include: electing not to pursue enforcement action, grouping violations to reduce the magnitude of the enforcement action, or mitigating a civil penalty. However, as discussed previously, enforcement discretion can also be used to escalate the magnitude of an enforcement action in appropriate circumstances

A decision to not pursue an enforcement action is generally based on meeting all of the following criteria:

- The noncompliance is promptly identified by the contractor prior to some self-disclosing event, and reported into NTS or

the contractor's self-tracking system consistent with reporting thresholds.

- The violation is not willful or a violation that could reasonably be expected to have been prevented by the DOE contractor's corrective action for a previous violation.
- The DOE contractor, upon discovery of the noncompliance, has promptly taken or begun to take action to correct the condition.
- The DOE contractor has taken, or has agreed to take, comprehensive corrective actions.
- The event is not a serious or potentially serious event.

When an enforcement action will be taken, the decision to apply discretion and to aggregate violations that normally would be cited separately, thus reducing the potential magnitude of the enforcement action, is generally based on (A) the unusually positive actions by the contractor in identifying and correcting the violations, or (B) recognizing other ongoing improvements that the contractor already had underway but had yet to be fully effective at the time the violations occurred.

Also, discretion may apply for latent conditions or legacy issues discovered by a contractor and likely due to the actions or inaction of a prior contractor. Whether to apply discretion will depend on several factors, including: whether the current contractor should have identified the problem earlier through routine activities such as surveillance, survey, or assessment activities; whether the current contractor should have identified the problem through a required inspection or baseline review; whether the current contractor should have identified the problem in its due-diligence reviews; or whether the current contractor was notified of the existing problem by DOE or the prior contractor. In any such cases, the current contractor must have taken prompt and appropriate action upon identification and properly reported the noncompliance condition to receive consideration for this application of discretion.

Ability of Contractor to Pay Civil Penalty

DOE's enforcement policies grant DOE discretion in adjusting civil penalties based on judgment of the ability of the contractor to pay. Although the policies generally take into account the safety significance of a violation as a primary consideration in assessing a civil penalty, the contractor's (including subcontractor's) ability to pay may be a secondary consideration. It is not the purpose of DOE enforcement actions to be so severe as to put the contractor into bankruptcy. Contract termination, rather than civil penalties, is used to terminate contractor activities for DOE. However, the burden of proving inability to pay is on the contractor and must be conclusively demonstrated by a present financial condition--not a future condition. If it appears that the economic impact of a civil penalty might put a contractor into bankruptcy, or interfere with a contractor's ability to safely conduct activities or correct the violation to bring its program into full regulatory compliance, or both, it could be appropriate to decrease the base civil penalty.

It is expected that this discretion would rarely be used. Economic hardship must be clearly demonstrated by the contractor. The Director may also request assistance from other DOE offices to substantiate a mitigating financial condition.

Consent Order

Contractors are provided opportunities to seek settlement with

DOE through a consent order for a matter involving safety noncompliances that potentially could have proceeded to an investigation and possible enforcement actions for both nuclear and worker safety and health matters (reference Part 820.23 and Part 851.41, respectively). A consent order is a document, signed both by the Director and a contractor, containing stipulations or conclusions of fact or law, and a remedy acceptable to both DOE and the contractor.

Consistent with DOE policy that encourages settlement of enforcement proceedings at any time, the Director and the contractor can meet at any stage of the process and reach a settlement in the form of a consent order. The consent order will identify the relevant facts related to specific safety requirements and the remedy that is agreed. It need not include a finding that a violation has in fact occurred, and the contractor is not necessarily required to admit that any such violations occurred.

Contractors submitting a request to OE for consideration of a consent order must demonstrate a history of strong, proactive safety performance, coupled with an aggressive investigation of the subject issues and comprehensive corrective actions. OE recognizes the potential for a contractor with a positive safety record to have an occasional event or other noncompliance issue that would justify consideration of potential enforcement action. However, in evaluating a request for a consent orders, OE will consider the contractor's performance history over an extended period, about two years in most cases. OE expects the contractor to demonstrate a consistent proactive approach to the anticipation, comprehensive investigation, and resolution of nuclear safety and worker safety and health issues, or have a performance history that is reflective of a consistent improving trend in performance.

A contractor organization that cannot demonstrate such consistent proactive behavior should not expect favorable action on a request for a consent order solely on the basis of recent aggressive action to deal with nuclear safety issues, worker safety and health issues, or both. Such recent proactive behavior may justify application of enforcement discretion or mitigation consideration in a possible enforcement action, but would not justify the use of a consent order. In this regard, Part 820, appendix A, section IX, and Part 851, appendix B, section IX, describe the means by which OE can apply enforcement discretion or mitigation or both for initiative in promptly identifying, reporting, and correcting nuclear safety and worker safety and health-related problems, including investigation efforts, cause analysis, and corrective action development and implementation. It is important that the DOE contractor community understand the above-discussed distinction between circumstances that warrant application of discretion or mitigation of an enforcement action versus those circumstances that merit the use of a consent order.

It is in the contractor's best interest to submit its request for a consent order as early as possible, and not delay it until after OE has notified the contractor via correspondence of its intention to launch a formal investigation. Consent order requests must be accompanied by supporting documentation (if not provided already to OE through informal means prior to the consent order request), including, but not limited to:

- Factual description of the event.
- The contractor's investigation and assessment of specific root causes.
- A summary of the contractor's enforcement history during the 24 months preceding the event.

- Evaluation of the contractor's NTS reporting activity for the preceding 24 months, if available (level of reporting, extent to which issues are being proactively identified through assessment versus being disclosed through response to events, rigor of actions being taken, results of effectiveness reviews).
- A listing of comprehensive corrective actions developed and implemented as a result of the findings set forth in the contractor's investigation with objective evidence of completion.
- Performance indicator information used to monitor the effectiveness of nuclear and worker safety implementation.

In making the final determination, OE will review the scope, thoroughness, and quality of the contractor's investigation. The contractor must demonstrate that corrective actions are timely and appropriate in scope and content and, when fully implemented, will resolve nuclear safety and/or worker safety and health problems.

OE will also consult with and take into account the views and recommendations of DOE and NNSA headquarters line management personnel, and Field Office personnel who have responsibility for safe operations of the various facilities in question. In addition, OE may solicit input from colleagues elsewhere in DOE who have conducted oversight reviews at the sites and facilities of interest. Finally, OE will review other sources of information on contractor safety performance, which may include:

- Results of contractor program reviews.
- Consistency in NTS reporting.
- Relevant assessments performed by the DOE Office of Independent Oversight.
- ORPS reports.
- Nuclear safety and worker safety and health program indicators.

In choosing to issue a consent order, OE is exercising enforcement discretion based upon the contractor's aggressive response to the event and its judgment that the contractor has generally demonstrated positive safety performance. OE will continue to coordinate with the Field Office to monitor progress on the implementation of corrective actions, as appropriate, and the overall effectiveness of applied controls.

The use of a settlement agreement in the form of a consent order is mutually beneficial to both DOE and the contractor. The consent order is issued in lieu of a potential investigation by DOE and possible enforcement proceedings, including the potential issuance of an NOV with the imposition of a civil penalty. The monetary settlement between DOE and the contractor represents an agreed amount in lieu of any subsequent investigation and the agreement that DOE will not pursue an enforcement action or civil penalty for any potential violations pertaining to the event. However, DOE may subsequently consider enforcement action if it later becomes known that any of the facts or information provided were false or inaccurate, or if commitments to take corrective actions have not been met. There will be no press releases involving consent orders.

OE encourages the application of this approach whenever appropriate. However, it is incumbent upon OE to apply this tool in a consistent manner and to assure that, when it is applied, it is

in the best interest of DOE to do so.

Compliance Order

The authority of the Secretary to issue a compliance order is established both for worker safety and for nuclear safety violations (Part 851.4 and Part 820, subpart C). A compliance order is generally considered in circumstances where an immediate and serious safety problem exists, repeated efforts by DOE to assure completion of appropriate corrective actions by the contractor to resolve safety problems have failed, and a significant safety deficiency is continuing. In such a case, OE, in consultation with Field and Program Office management, would commence the preparation of the compliance order, including briefing material for the Secretary. A compliance order may only be signed by the Secretary.

The compliance order would generally identify violations of nuclear safety regulations, worker safety and health regulations, or both and describe the conditions or underlying problems that have not been adequately corrected, specific actions required to be completed by the contractor, the basis for the actions, and required dates for completion of those actions. Requirements in the compliance order are effective immediately, unless a specific effective date is specified in the order. For worker safety violations, the contractor is required to post the compliance order in a prominent location at or near where the violation(s) occurred and the order must remain posted until the violation(s) is or are corrected.

Within 15 calendar days of the issuance of a compliance order, the recipient of the order may request the Secretary to rescind or modify it. A request does not stay the effectiveness of a compliance order unless the Secretary issues an order to that effect.

Failure to comply with a compliance order could subject the recipient to further enforcement action, including applicable civil penalties.

In addition to the compliance order, DOE may also issue an enforcement action with corresponding citations for the violations that have occurred and impose appropriate civil penalties.

Administrative Matters

Docket File

Part 820.10 specifies the establishment of Office of the Docketing Clerk for nuclear safety matters, with responsibilities for maintaining docket files for each enforcement case, exemption decisions, interpretations, as well as maintaining files of approved nuclear safety program plans. The Docketing Clerk is also assigned responsibilities for notification and filings associated with any adjudication proceeding. To implement these requirements and responsibilities, the Office of the Docketing Clerk has been established in OE.

Part 851 does not establish any similar formal requirements for the Docketing Clerk. However, as a matter of practice, the OE Docketing Clerk will perform similar functions for worker safety matters. For each enforcement case involving worker safety violations, the Docketing Clerk will maintain a docket file. In addition, the Docketing Clerk will maintain copies of approved Safety and Health Plans and approved variances to Part 851 that are provided to OE.

Assignment of Enforcement Action Number

An enforcement action (EA) number is assigned to each proposed enforcement action by the Office of Docketing Clerk after a decision is made to issue a PNOV. It is a method of administratively docketing and tracking cases. EA numbers are assigned sequentially according to the year of issuance (e.g., EA 06-01, EA 06-02, etc.). Once an EA number has been assigned to an enforcement matter, all subsequent filings, memoranda, and correspondence for that case should include the case name and its complete EA number. Enforcement action numbers are assigned for NOVs and compliance order cases.

Target Enforcement Process Schedule

OE attempts to move as expeditiously as possible in each enforcement case, within the limits of staff availability and existing case load. The following are guidelines that OE will attempt to follow, but prior workload or circumstances of a particular case may dictate changes from these targets. The Director has the discretion to decide case priority and the schedule to be followed for each case.

To maximize the opportunity for expeditious completion of an enforcement proceeding, the conference should usually be scheduled within four weeks after completion and issuance of the OE investigation summary report. As a minimum, OE will provide the contractor with at least two weeks notice of the intent to conduct a conference.

Following an enforcement conference, OE will, generally, issue its decision, typically a PNOV, within four weeks. An FNOV, if issued, will generally be released within four weeks after receipt of a substantive response from the contractor either denying the violation or seeking further mitigation of the severity level or civil penalty.

Press Release

Press releases are generally issued for PNOVs, and are discretionary for other enforcement actions. After the enforcement action has been signed, the Director will forward the package to the contractor by e-mail, so the contractor receives immediate notice of the action, as well as the official copy via certified mail. OE generally prepares the draft press release and assists the DOE Office of Public Affairs in completing it. Generally, the contractor organization involved is given notice about two hours before a press release is issued and the enforcement action posted on OE's web site.

Release of Predecisional Enforcement Information to the Contractor and the Public

Investigation-related information is confidential and considered pre-decisional. For example, during the investigation phase of a case, discussions within DOE on planned areas or issues to investigate, lines of inquiry, preliminary conclusions on potential violations, and preliminary conclusions on mitigation factors are confidential to the investigation team and are not released to the public or the contractor.

Additionally, following the enforcement conference, information pertaining to any pending enforcement action is pre-decisional, and should be treated carefully. The Director, in consultation with appropriate DOE officials, is responsible for all decisions regarding the release of pre-decisional information to contractors

and to the public. Such information includes matters such as potential violations to be cited, potential severity level of the alleged violations, civil penalty amounts, and the nature or context of a PNOV.

The following criteria are followed by OE and should similarly be followed by other DOE personnel who have access to enforcement-related information for input, validation, or action:

- No information is released to the contractor or the public on the findings or conclusions of the investigation.
- The investigation summary report is released to the contractor as part of the ongoing enforcement proceeding to ensure the accuracy of facts, contractor understanding of alleged noncompliances, and support contractor preparation for any subsequent enforcement conference. The investigation summary report is pre-decisional and is not to be released to the general public. It is privileged and confidential.
- No information on a pending enforcement action will be released to the public or the contractor following an enforcement conference and prior to the issuance of a PNOV without the authorization of the Director.
- Pre-decisional enforcement information will only be released to the contractor when necessary to ensure that prompt corrective actions are taken to address a safety matter that is not already being addressed.
- Upon issuance of a PNOV, the DOE transmittal letter and PNOV will be placed in the OE docket file and on the OE web site. Only then is this information available to the general public.
- For nuclear safety matters, after issuance of a PNOV and prior to the issuance of a final order, any meetings or conferences between DOE and the contractor pertaining to the enforcement action shall be transcribed as required by Part 820.10(c).
- An enforcement case is not closed until all corrective actions have been completed. Subsequent to that time, records pertaining to the final decision may be made available to the public.

Closing a Case

A particular enforcement case is not closed by OE when a contractor concedes the violation and pays any civil penalty. DOE will keep an enforcement case open until it has confirmed through the NTS that appropriate corrective actions have been completed. If corrective actions are not completed in a timely manner or if DOE Field Office personnel find that the corrective actions were not properly completed, OE could decide to take further enforcement action. Such further enforcement action could include issuance of a subsequent PNOV.

VIII. Application of Enforcement to Special Conditions

General Enforcement Approach

Recurring/Repetitive Problems

Chapter IV noted that this condition is one that should lead to an NTS report. Also, chapter VI notes that this is a condition that factors into OE's consideration of safety significance when reviewing NTS reports or other initial identification of noncompliance conditions, and making decisions on cases to investigate. Also, chapter VII identifies this condition as one that impacts the enforcement action outcome, usually causing OE to apply less mitigation in the corrective action area, as well as often leading to a Quality Improvement citation for a nuclear safety violation.

It is unfortunate that in a large percentage of all the cases it investigates, OE has found that recurring issues are involved, i.e., problems identical or similar to those that have led to a serious event or condition had occurred previously within the same organization, facility or site. When problems recur, corrective action management processes are inherently flawed, in that either the corrective actions taken in the prior circumstances were not effective in preventing recurrence, or the corrective actions were not maintained. In turn, this means that causal analysis deficiencies may exist, that trending processes are not sufficiently developed, that extent of condition reviews are not being done or not being done effectively, or that performance assessment processes are not discovering issues before they result in significant safety events, or both. As a generalization, senior management attention too often is focused on safety only following a very serious event or an enforcement action. In INPO's terms (one of that organization's eight principles that form the basis for an excellent safety culture), leaders have not sufficiently demonstrated (as opposed to talked about) a commitment to safety.

The condition described above is unacceptable at this stage of maturity of the DOE Complex, in that it demonstrates that insufficient management attention is being placed on appropriate responses to safety events, but also on finding the precursor issues that, when properly addressed, will prevent those events from occurring in the first place. As a result, OE has put the contractor community on notice that enforcement actions that involve recurring issues will involve a significantly greater civil penalty than would otherwise have been the case. This may include greater use of DOE's "per day" authority discussed previously, separate citation of violations rather than aggregation, escalation of the severity level of the violations, or a combination of these remedies depending upon the circumstances.

As for the potential underlying problem area(s) that can contribute to a recurrence of problems, OE has provided lesson-learned information in two appendices to the Program Plan. In particular, the information in appendix F addresses contractor investigation, causal analysis, and corrective action deficiencies that have been observed by OE. Appendix G addresses contractor assessment program deficiencies observed by OE.

Contractor Transition

DOE's sites or facilities will, from time to time, transfer management and operation responsibility to a different contractor, and appropriate planning and transition for compliance with DOE nuclear safety requirements is required. The process of transition will normally include a period of review and due diligence on the part of the incoming contractor. DOE's expectation per the regulations is that the outgoing contractor will have responsibility for compliance with DOE safety requirements during the period of its contract, up to and including the date of turnover to the incoming contractor. DOE could pursue an enforcement action, even after turnover, with the outgoing contractor for any case of noncompliance that occurred during the contract period.

The incoming contractor organization is expected to assume full responsibility for safe operation and compliance with DOE safety requirements on the date it assumes contract responsibility for the site or facility. The incoming contractor would normally identify during the due-diligence review significant individual or programmatic issues of noncompliance with DOE safety requirements, and these would be addressed with the appropriate DOE Field and Program Office managements prior to assuming responsibility for the site or facility. Additionally, after assuming responsibility, the incoming contractor should (A) report noncompliance conditions identified during this due-diligence period that meet NTS reporting threshold criteria, and (B) assume from the outgoing contractor responsibility for completing or assuring completion of corrective actions and problem resolution that were still ongoing at the time of turnover.

OE intends to exercise reasonable discretion in considering a noncompliance issue that surfaces in the near term after the incoming contractor assumes responsibility, and that could not have reasonably been identified during the due-diligence period. OE will generally forego pursuing enforcement action during this early, near-term period if the contractor, upon identifying the condition, reports this noncompliance condition to the NTS or its internal tracking system (as appropriate) and responds with timely and effective corrective actions. However, for serious events or accidents such as serious worker injury, or substantial actual or potential radiological uptake or exposure, OE would generally not exercise such forbearance.

Accuracy of Information/Willful Violation

DOE relies on the accuracy and completeness of information provided by its contractors. Part 820.11, *Information Requirements*, requires that any information, pertaining to a nuclear activity, provided to or maintained for DOE by a contractor shall be complete and accurate in all material respects. Similarly, Part 851.40(b) requires contractors to provide complete and accurate records and documentation to OE in support of investigation activities. Noncompliances with these requirements could involve either intentional or unintentional conditions. Unintentional errors in safety documents and records are undesirable nonetheless, should be considered noncompliances with the above referenced regulations, and should be reviewed for possible reporting into the NTS. Intentional errors, such as falsification, destruction, or concealment of records or information should be treated as a willful violation and addressed as discussed below.

A willful noncompliance with a nuclear or worker safety requirement receives close attention by OE. As noted in

chapter IV, such a noncompliance should be reported into NTS. Chapter IV also describes certain attributes that OE looks for in considering whether a condition is a willful noncompliance. Additionally, as noted in chapter VI, such a condition is considered more significant than the safety significance of the corresponding noncompliance itself when reviewed by OE for possible investigation. A willful violation is considered significant *per se*, regardless of the issue to which it pertains.

Department of Justice (DOJ) Referral

Part 820 states DOE may refer a nuclear safety matter to DOJ if DOE believes a criminal action has occurred. Although not specified in Part 851 for worker safety issues, OE, as a matter of practice, will follow the same approach as for nuclear safety matters that are believed to involve a potential criminal action. As a general policy, if a matter has been referred to DOJ, in the absence of an immediate need to take action for health and safety reasons, issuance of a DOE enforcement action would be held in abeyance. The purpose of this postponement is to avoid potential compromise of or conflict with the DOJ case, pending DOJ concurrence that the enforcement action will not affect any potential prosecution. The Director is responsible for coordinating enforcement matters with DOJ.

It is expected that if DOJ determines that a referred case lacks prosecutorial merit, it will notify DOE by a letter of declination. When this is received, the Director will then determine whether to proceed with an enforcement action. Proceeding with enforcement would then follow the same process described in this document.

Suppliers and Subcontractors

An NOV may be issued to a subcontractor or supplier who fails to comply with DOE safety requirements. For nuclear safety issues, enforcement regarding any subcontractor or supplier to a Price-Anderson indemnified DOE contractor is addressed in the enforcement policy, appendix A of Part 820. Nuclear safety rules Parts 820, 830, 835, and 708 apply directly to these indemnified subcontractors and suppliers. Noncompliance with such requirements are subject to the same enforcement process described in this Program Plan.

In the worker safety area, Part 851 applies directly to DOE contractors as well as to their subcontractors that have responsibilities for performing work at a DOE site in furtherance of a DOE mission, subject to certain exclusions. DOE may issue an enforcement action to a contractor or subcontractor for violation of a Part 851 requirement. Part 851 also permits the imposition of a civil penalty for an indemnified contractor including any associated subcontractor, with certain limitations as specified in the rule.

In general, DOE holds its prime contractors primarily responsible for safety at their respective sites of employment, and will many times issue a NOV to the prime contractor for any violation by its subcontractor when an enforcement action is determined appropriate. However, depending upon the circumstances, an enforcement action may also be taken against the subcontractor, either alone or in addition to that taken against the prime.

Management and Independent Assessment Programs

Over the past few years, OE has stressed the importance of

contractor assessment programs as an effective tool in proactively identifying conditions adverse to quality before those deficiencies manifest themselves in significant safety events.

The Director has emphasized the importance of shifting from an event-driven to an assessment-driven culture and established a goal of having the great majority of all NTS reports being identified through contractor internal assessment activities by 2008. The term "assessment" is not meant to imply only those activities associated with formal management and independent assessments. Rather, the term is meant to include other self-identifying activities such as audits, engineering reviews, surveillances, and even problems/event precursors that are identified by workers and supervisors during routine performance of their activities.

It is recognized that the determination of an event-driven versus an assessment-driven NTS report is not always black and white and may involve some level of subjectivity. It is also recognized that many issues in contractor internal tracking systems are uncovered by assessment activities. However, the mere fact that a self-disclosing event not explicitly meeting an NTS reporting threshold is reported, due to a management concern, does not imply self-identification through assessment. The important objective is to reduce the number of safety events and significant near misses by improving performance assessment processes.

The cases that OE pursues for investigation and enforcement action also are largely events that disclose underlying safety and management issues. These are almost always issues that were identifiable through an effective assessment process. However, contractor assessment processes have been deficient in failing to find the problems before they were disclosed by an adverse event. Appendix G provides background on some of the common assessment program deficiencies noted by OE, as well as summarizing the assessment program review approach used by OE in its PAAA program reviews or investigations. OE regularly cites in its enforcement actions assessment program deficiencies that contribute to the event under investigation. In this regard, OE encourages the DOE community to review and use the performance assessment guide prepared by the EFCOG PAAA Working Group as a starting point toward improvement of assessment processes. The guide is available at the EFCOG web site.

DOE Contractor Employee Protection Program

The DOE Contractor Employee Protection Program, established in Part 708, applies to complaints of reprisals or retaliation against DOE contractor employees for certain conditions (protected activities) including: employee disclosures, participations, or refusals related to various matters including both worker and nuclear safety and health issues. Specifically, Part 708 provides employees with a process to file a complaint concerning retaliation and to obtain restitution from the contractor in the event of a finding of reprisal under the rule.

In the relevant Federal Register notice adopting Part 708, Part 708 was designated a nuclear safety rule enforceable under the PAAA. Additionally, Part 708 states that, to the extent an act of retaliation by a DOE contractor results from an employee's involvement in matters of nuclear safety in connection with a DOE nuclear activity, the retaliation could constitute a violation of a DOE nuclear safety requirement and could warrant relief to the employee under Part 708 and the imposition of civil penalties on the DOE contractor under Part 820.

The *Worker Safety and Health Program* final rule, Part 851, contains, in section 851.20, specific worker safety and health rights that parallel the employee-protected activities of Part 708. Acts of retaliation involving worker safety issues could warrant relief to the employee similarly, as described above, under Part 708 as well as the imposition of civil or contract penalties on the DOE contractor under Part 851.

Based on the above, the OE has the authority to issue civil penalties against the company responsible for retaliation associated with protected activities involving either nuclear or worker safety and health matters. The enforcement activities conducted by OE are for the purposes of issuing NOVs and civil penalties to DOE contractor entities in an effort to prevent acts of retaliation and to address violations of DOE nuclear and worker safety rules as discussed above.

It is important to note that the process for reviewing complaints and authorizing remedies to the individual complainant does not reside with OE, as discussed in more detail below. Employees subjected to and seeking appropriate resolution of a potential act of retaliation need to follow the process described in Part 708. Any activities conducted by OE can not be viewed as a substitute for following Part 708 procedures.

The procedures for the implementation of Part 708 provide an individual with multiple options for pursuing a remedy for retaliation. Generally, such matters can be heard either by the DOE's Office of Hearings and Appeals (OHA) or by the U.S. Department of Labor (DOL). There are procedural and other reasons for selecting an appropriate forum for the matter and that choice will not in any way affect the manner in which the issue is addressed by OE. In general, and in an effort to conserve limited governmental resources, OE, as a matter of practice, plans to defer acting on a retaliation matter against a DOE contractor until OHA or DOL has completed its investigation, hearing, initial decision, and final agency decision. While OE has in one case deferred a matter (SEC enforcement action, June 2005) until it was dismissed on appeal by a U.S. District Court, it has been concluded that such a deferral in the future is not generally appropriate. The purpose of any deferral is to avoid a duplication of government investigation and adjudicatory resources in pursuit of an appropriate remedy. It is clear that, barring unforeseen circumstances, the record is generally complete when an agency issues a final order. Therefore, even if a matter is appealed at that point, OE intends to commence its enforcement activities.

It is also important to note that, although OE will defer commencement of enforcement activities as it relates to an act of retaliation (as described in the preceding paragraph), OE will address any associated substantive nuclear or worker safety issue that represents a noncompliance, consistent with normal OE processes as described in this Program Plan. Such a noncompliance could lead to an OE investigation and an enforcement action solely intended to address the nuclear or worker safety rule violation well prior to issuing an action related to the act of retaliation.

There are many factors associated with retaliation cases that will be considered when exercising OE's enforcement discretion. Examples are the magnitude of the retaliation, the management level associated with the retaliation, the response of the DOE contractor subsequent to the retaliation with respect to its work force, and the overall record of the contractor with respect to nuclear safety. Positive performance would not likely lead to avoiding action on the retaliation, but could impact mitigation

consideration, and negative performance could be a factor in considering enforcement escalation. Another consideration is whether the adverse action is in response to an employee coming to DOE or another government agency. The ultimate decision whether to take enforcement action with respect to a claim of retaliation also does not in any way depend on whether the underlying nuclear or worker safety concern proves to be valid. In other words, the act of retaliation is itself a safety concern, because of the chilling effect it has on the willingness of employees to speak up when safety issues exist.

Two cases of record involving such potential retaliation may be viewed on the OE website. As described in an enforcement letter of April 19, 2005, an employee at the Savannah River site was dismissed and maintained that retaliation was a factor in the decision. After an analysis and report by a contractor team, the employee was rehired and provided with an equivalent position. An enforcement letter was issued to express DOE's concern regarding this matter.

In EA 2005-03, dated June 14, 2005, Safety and Ecology Corporation (SEC) was issued an NOV for retaliating against an employee by terminating employment. Although the former employee prevailed on the facts before both a hearing examiner and the head of OHA, the matter was taken by the company to US District Court, where a Motion for Summary Judgment filed by the government was granted. In addition to the reinstatement, back pay, and SEC's attorneys' fees, SEC was issued a civil penalty as a result of OE's enforcement proceeding. SEC incurred further expenses in the matter since, under the *Major Fraud Act*, it was responsible for segregating non-compensable costs associated with all proceedings.

Nuclear Safety and Worker Safety and Health Noncompliances

OE has observed over the past several years a number of examples of cases that involved both nuclear safety and worker safety issues. These can include, for example, a fire or explosion that affected or may have affected radiological materials and worker safety, violation of lock-out/tag-out requirements affecting nuclear safety systems and the potential for an electrical shock, or a series of both nuclear and worker safety events that demonstrated a programmatic problem in work planning or execution. Since the WSH rule was not issued at that time, the enforcement actions focused on and cited only the related nuclear safety violations.

It is expected that, from time to time, such cases with implications in both nuclear and worker safety areas will continue to surface. With the issuance of Part 851 in February 2006, if such a case occurs, OE will generally conduct an integrated investigation that reviews the facts, circumstances, and noncompliances that occurred in both areas.

Additionally, if OE elects to pursue an enforcement action for noncompliances in both areas, this would generally be a combined action by citing both nuclear and worker safety violations. These will be coordinated so that the same violation is not cited twice and with civil penalties in both the worker safety and nuclear safety areas. That does not mean that a single event or occurrence might not have certain noncompliances in the worker safety area and certain other noncompliances in the nuclear safety area. Coordinating reviews and enforcement proceedings for both areas ensures there is proper consideration of the diverse noncompliances that may have occurred.

Enforcement Approach for Selected Worker Safety Issues

Pending Part 851 Variance Requests

OE anticipates that certain contractors may not have pending variances approved by the required Part 851 compliance date of May 25, 2007, due to limited DOE resources and time available for variance review and approval. The following addresses conditions where OE may apply enforcement discretion when a violation involves a regulatory provision of 10 CFR Part 851 for which the contractor has a pending variance request. The process described is similar to the approach OE implemented concerning a backlog of pending contractor exemptions during the early stages of 10 CFR 835 implementation.

As noted earlier in this Program Plan, the intent of the enforcement process is to promote and protect the safety and health of workers at DOE facilities. OE has substantial authority to exercise discretion in the application of enforcement mechanisms.

DOE acknowledges that its contractors, in pursuit of compliance with Part 851, may be in a position were they have submitted requests for variances in a timely manner from certain provisions in accordance with the requirements of Part 851, subpart D. Due to the intensive effort required to process and decide these variance requests in accordance with the applicable regulatory requirements, some contractors may be waiting for final action by the Department regarding these requests and, thus, find themselves potentially in a condition of noncompliance as of the required compliance date. To the extent that the identified contractors have taken action in good faith and have implemented any necessary interim protective measures or compensatory actions to provide for adequate worker protection, application of the Department's enforcement authority would not advance the Department's goals as stated in appendix B of Part 851. In these narrow cases, OE does not intend to take enforcement action against those contractors for a noncompliance for which a variance has been requested but has not yet been acted upon by DOE. However, this policy does not apply to variance requests submitted after May 25, 2007. It is important to emphasize that the exercise of such discretion depends upon a good faith, timely submission by the contractor that completely addresses the requirements of Part 851.

Multiple Employer Worksite

Many DOE sites have multiple contractors and subcontractors performing work at the same workplace, which can make managing worker safety and health more challenging. Subparts B and C of Part 851 contain comprehensive requirements that each contractor must follow to protect its employees. But, given the complexity of working with other contractors and subcontractors on site, coordination of work planning and execution to ensure worker safety and health must be given special consideration.

If a matter involving risk to workers from multiple contractors is selected by OE for investigation, OE will determine the full extent of responsibility among those contractors for exposing employees to hazards. In such cases, OE's investigation will focus on determining which contractor(s): A) created the hazard; B) had responsibility for correcting and controlling the hazard; and C) exposed the employees to the hazard.

OE will review available records and procedures that describe

roles and responsibilities, determine whether responsible employees have received appropriate training, and ascertain actual practices and conditions in the workplace to establish the extent of contractor responsibility. OE may cite any contractor found responsible, whether or not the contractor's own employees were exposed to the hazard in question.

If an enforcement action is taken, OE will also consider both mitigating and aggravating circumstances for each contractor involved in accordance with the enforcement process described in this Program Plan. At a minimum, DOE would expect a contractor whose workers are exposed to a hazard to promptly correct the hazard if it has the authority to do so or to remove its workers from the exposure in a timely manner, adequately protect its employees, and promptly notify that contractor having the responsibility to correct the hazard.

General Duty Clause

DOE will take enforcement action against a contractor who fails to provide a place of employment that is free from recognized hazards that are causing, or have the potential to cause, death or serious physical harm to workers, in accordance with Part 851.10(a). The intent of Part 851.10(a) is to parallel the requirements set forth in OSHA's general duty clause, section 5(a)(1) of the *Williams-Steiger Occupational Safety and Health Act of 1970* (29 USC 654).

DOE contractors have a clear obligation to protect workers from death and serious physical harm resulting from recognized workplace hazards, even where:

- There is no existing standard that covers the hazard.
- There is doubt whether a particular standard applies to the hazard.
- A particular safety and health standard is inadequate to protect the contractor's workers against the specific hazard the standard addresses and the contractor is aware of the inadequacy.

In such situations, contractors must take whatever abatement actions are feasible to eliminate such hazards. If a hazard meets the conditions outlined below, a contractor will be considered to be in noncompliance with Part 851.10(a) and may be subject to appropriate enforcement action and penalties:

- *The condition presents a hazard to which workers are exposed.* This means that the hazard exists, workers are exposed to the hazard, and the contractor has failed to remove the hazard. A hazard is defined as a "danger which threatens physical harm to employees." The contractor is not expected to follow any pre-defined abatement method, step, or precaution but to use any and all feasible means to protect employees from the hazard.

  It is also important to attempt to foresee the existence of a general workplace hazard that may lead to a condition that creates another hazard or may result in an event. Evidence of the existence of an undetected hazard may be provided by the occurrence of an event, especially if it results in an injury or fatality. Contractors must be constantly vigilant to detect and correct any existing hazard as well as any new hazard, e.g., that which may result from a change in a process or work practice, or from the use of new or additional equipment.
- *The hazard is a recognized hazard.* This means that the contractor knew or should have known about the hazard in

the situation, the hazard is obvious, or it is a recognized one within the contractor's industry, i.e., the hazard is identified and addressed in a recognized industry consensus standard, or other credible industry guidance or documentation. Use of a work practice that is contrary to an accepted industry practice or standard, or contrary to a supplier's standard for use, or that safety experts in the industry acknowledge creates a particular hazard, would mean that the employer should have known about the hazard.

Recognition of a hazard by a contractor is also evidenced by the contractor documenting or reporting any injury related to the hazard as well as by workers calling the contractor's attention to the hazard. Any written or oral statements made by the contractor or a supervisor that relates to the hazard also establishes knowledge of the hazard.

For a hazard that is unrecognized by the industry, DOE would still hold a contractor responsible for recognizing and correcting the hazard if DOE concludes that the hazard should have been recognized by a reasonable person.

- *The hazard is causing or has the potential to cause death or serious physical harm.* The hazard must be classified as Severity Level I or serious, meaning that there is a potential that a serious injury, illness, or death could result if the hazard is not eliminated or controlled. This can include any potential acute or chronic impairment of the body that affects life functioning on or off the job (usually requiring treatment by a medical doctor), whether temporary or permanent. Or this could be any illness that significantly reduces physical or mental efficiency, e.g., occupational asthma.
- *Feasible and useful methods exist to correct the hazard.* The hazard must be correctable, i.e., there is a feasible and known way for the employer to correct, eliminate, or at least significantly reduce the hazard through either applying an appropriate control or having workers use adequate personal protective equipment.

Employee Misconduct

[To be provided at a later date.]

Coordinating Application of Civil Penalty and Contract Fee Reduction

10 CFR Part 851.5 states that contactors indemnified under the *Atomic Energy Act* (AEA) are subject to either civil or contract penalties, but not both. In addition, Part 851.1 states that only contract penalties can be levied against non-indemnified contractors since they are not subject to civil penalties. The majority of DOE's contractors are indemnified under section 170d of the AEA. However, some contractors are not indemnified under section 170d, and, therefore, are handled under the contract remedy provisions of the rule. The preamble to Part 851 (see pages 6871 and 6876) also states that for a worker safety violation, the Director will coordinate with the appropriate DOE Program Office and Field Office contract representatives on the type of monetary penalty (either contract or civil) and the amount to be assessed.

The current enforcement process includes a determination by the Director, in consultation with the appropriate Program Office and Field Office, that an enforcement action will be taken against a contractor and that a monetary penalty will be assessed. In order to ensure an adequate level of consultation, OE already has built within its enforcement process certain coordination steps (see

chapter VI, *Investigation Process*) that ensure both DOE Program and Field Office representatives perspectives and views are considered throughout the entire enforcement process. OE is actively working with both DOE Program and Field Office representatives on revising its enforcement process to further address the added level of coordination needed to ensure effect implementation of both civil and contract penalties. Once completed, a description of the updated process will be included in a revision to this program plan.

Applicability of Part 851 and "Work for Others"

Part 851 states it applies to the conduct of contractor activities at DOE sites where a contractor is an entity under contract to DOE "that has responsibilities for performing work at a DOE site in furtherance of a DOE mission." Often, DOE facilities, particularly in the science arena, are made available to representatives of various institutions, companies, and foreign organizations to conduct various research studies and activities. Questions have been raised as to whether enforcement would apply to worker safety issues that involve such workers performing research for others using DOE facilities.

The key issues are (1) whether such work is "in furtherance of a DOE mission," and (2) whether the entity represented by such workers are DOE contractors. On the first issue, DOE's current Strategic Plan[6] includes, as one of the strategic goals to accomplish DOE's mission, providing "world-class research facilities for the Nation's science enterprise…that support advancements in practically every field of science." As such, the work by visiting research personnel using DOE's facilities clearly fits within DOE's mission.

On the second issue, as to whether these individuals are working for a DOE contractor, OE has requested DOE's Office of General Counsel to provide clarification. The issue is whether the arrangement, agreements, or permits that support such use of DOE facilities may be considered as contracts, and thus their employers as "contractors" within the meaning of such in Part 851. OE's enforcement practices will be governed by this forthcoming guidance, and this Program Plan will be updated when it becomes available.

Legacy Worker Safety Issues

It is expected that some pre-existing conditions at various DOE facilities will be found that are not in compliance with Part 851 requirements, and that facility changes to come into compliance may be impractical and expensive. Anticipated issues involve existing code of records that predate and are different from Part 851 requirements, previously granted equivalencies to Part 851 referenced standards, adequacy of existing abatement strategies to known noncompliances, and other similar issues. OE expects that guidance will be forthcoming from subject matter experts in this area. OE guidance on enforcement in this area will be developed when further DOE guidance on approaches to implementation is available.

Enforcement Approach for Selected Nuclear Safety Issues

Violation of Quality Assurance (QA) Requirements

As part of routine investigations and enforcement activities, OE has encountered various situations in which DOE and contractor

[6] *The Department of Energy Strategic Plan*, September 30, 2003.

organizations have incorrectly exempted activities from compliance with the quality assurance requirements of 10 CFR Part 830, subpart A. Examples of this include inappropriately limiting the application of subpart A to only one or more of the following:

- A limited set of facilities (hazard category 3 and above), or a limited set of equipment or operations as defined in or described within safety basis documents, or both.
- Work involving only a physical activity or the direct handling of radiological material, or both.
- Only when nuclear or radiological material is present in a facility.

In some cases, these applicability issues have led to events and enforcement actions where a key contributing cause was a failure to apply either adequate work control processes or QA controls consistent with the contractor's quality assurance program and rule requirements. Appendix H provides guidance on relevant subpart A requirements and the DOE General Counsel 95-1 interpretation as they relate to these applicability issues. Also provided is additional discussion on each of the three specific issues or potential problem areas noted above and OE's general enforcement approach.

Internal Dosimetry Program Issues

During the early implementation of Part 835, confusion regarding the internal dosimetry monitoring threshold contained in Part 835.402 (radiological workers "likely to receive" 100 millirem) led to a number of questions related to the enforcement of such a threshold, and the potential liabilities associated with implementation of a discretionary monitoring program. OE subsequently (in 1999) issued guidance clarifying the enforcement approach to reviewing such discretionary monitoring programs, the crediting of respiratory protection devices in estimated internal doses, and the relationship of monitoring thresholds to As Low As Reasonably Achievable (ALARA) programs and enforcement threshold values. That guidance has been updated and is included in appendix E.

Discovery and Control of Legacy Contamination

Legacy radioactive contamination has been generally defined as radioactive contamination resulting from a historical operation that was unrelated to current activities. OE's early experience with legacy contamination issues was that several contractors advanced the view that, since the contamination was "legacy" and occurred during a previous contractor's activities, the discovery fell outside the scope of Part 835 and therefore did not represent a noncompliance. There was also a mistaken perception within the contractor community that as long as legacy contamination remained undiscovered, it created a defense to an enforcement action. This perception was of particular concern to OE, since it acted as a disincentive to implementing a proactive and effective survey program. Thus, OE decided that enforcement discretion would only be applied to a legacy contamination situation in which an effective survey program was already in place. See appendix J for further details.

Nuclear Weapons Program

OE receives questions or concerns from time to time concerning the enforcement of Part 830, subpart A, associated with nuclear weapon programs. To address the requests for clarification, OE

has developed additional enforcement guidance for this issue in appendix I to this Program Plan.

Appendix A - Reporting Nuclear Safety Noncompliances[1] into NTS (see chapter IV for use of these thresholds)

Table A-1 - Noncompliances Associated With Occurrences (DOE Manual 231.1-2)

Reporting Criteria Group	Subgroup	Occurrence Category and Summary Description[2]
1. Operational Emergencies[3]	N/A	(1) Operational Emergency (2) Alert (3) Site Area Emergency (4) General Emergency
2. Personnel Safety and Health	B. Fires/Explosions	(1) Unplanned fire/explosion
3. Nuclear Safety Basis	A. TSR Violations	(1) Violation of TSR/OSR Safety Limit (2) Violation of other TSR/OSR requirement (3) Violation of DSA hazard control
	B. DSA Inadequacies	(1) Positive USQ
	C. Nuclear Criticality Safety	(1) Loss of all valid criticality controls
4. Facility Status	A. Safety Structure/System/Component (SSC) Degradation	(1) SSC performance degradation[4]
	B. Operations	(2) Actuation of Safety Class SSC (4) Facility Evacuation
5. Environmental	A. Releases	(1) Radionuclide release
6. Contamination/Radiation Control	A. Loss of Control of Radioactive Materials (RAM)	(1) Offsite RAM exceeding DOE limits (2) Loss of RAM (>100X 835 App. E)
	B. Spread of Radioactive Contamination	(1) Offsite radioactive contamination[5]
	C. Radiation Exposure	(1) Exceedance of DOE dose limits (2) Unmonitored exposure (3) Single exposure > thresholds
	D. Personnel Contamination	(1) Offsite medical assistance (2) Offsite personnel/clothing contamination (3) Onsite personnel/clothing contamination[6]
7. Nuclear Explosive Safety	N/A	(1) Damaged nuclear explosive (2) Introduction of electrical energy (3) Safety feature compromise (4) Inadvertent substitution (5) Violation of a safety rule (6) Damage to a training unit

Table A-2

Management Issues Noncompliances[7]
Repetitive Noncompliances
Programmatic Issue
Intentional Violation or Misrepresentation

Notes to Tables

1. Reporting noncompliances with any of the nuclear safety rules or other nuclear safety requirements.
2. These summary descriptions are a brief characterization of the related criteria. Use the full statement of the criteria contained in Manual 231.1-2 to establish NTS reportability of event-related nuclear safety noncompliances.
3. Report nuclear safety noncompliances associated with any of the M 231.1-2 Operational Emergency categories (Operational Emergency, Alert, Site Area Emergency, General Emergency).
4. Report noncompliances associated with a degradation of Safety Class Structure, System, or Component preventing satisfactory performance of its design function when required to be operable or in operation.
5. Report noncompliances associated with an offsite spread of contamination event where a contamination level exceeds 100 times the applicable value identified in 10 CFR Part 835, appendix D.
6. Report noncompliances associated with a personnel/personal clothing contamination where a contamination level exceeds 100 times the applicable total contamination value identified in 10 CFR Part 835, appendix D.
7. Refer to chapter IV for a description of these types of noncompliances.

Appendix B - Reporting Worker Safety and Health Noncompliances[1] into NTS (see chapter IV for use of these thresholds)

Table B-1 - Noncompliances Associated With Occurrences (DOE Manual 231.1-2)

Reporting Criteria Group	Subgroup	Occurrence Category and Summary Description[2]
2. Personnel Safety and Health	A. Occupational Illnesses/Injuries	(1) Fatality/terminal illness (2) Inpatient hospitalization of ≥ 3 personnel (3) > 3 personnel having DART cases (4) Personnel exposure > limits requiring medical treatment (5) Personnel exposure > limits (6) Serious occupational injury
	B. Fires/Explosions	(1) Unplanned fire/explosion within primary confinement/containment (2) Unplanned fire/explosion in a nuclear facility that activates a fire suppression system (3) Unplanned fire/explosion in a non-nuclear facility
	C. Hazardous Energy Control	(1) Process failure resulting in burn, shock (2) Process failure/discovery of uncontrolled energy source
10. Management Concerns/Issues	N/A	(3) Near miss

The simple occurrence of an event in any of the listed categories is not enough to warrant NTS reporting. Reportable noncompliances require the identification of a 10 CFR Part 851 noncompliance (e.g., 29 CFR Parts 1910 and 1926) in conjunction with the event. OE is interested only in those portions of the criteria with direct worker safety and health implications. Contractors identifying a significant worker safety and health noncompliance in association with an event type or category not listed on the table should evaluate the event for NTS reportability.

Table B-2 - Other NTS Reportable Conditions

Management Issues Noncompliances[3]
Repetitive Noncompliances
Programmatic Issue
Intentional Violation or Misrepresentation
Other Significant Conditions
Conditions meeting the criteria of Severity Level I (serious) violations > low relative risk[4]

Notes to Tables

1 Noncompliances with 10 CFR Part 851.

2 These summary descriptions are a brief characterization of the related criteria. Use the full statement of the criteria contained in Manual 231.1-2 to establish NTS reportability of event-related occupational safety and health noncompliances.

3 Refer to chapter IV for a description of these types of noncompliances.

4 Conditions of noncompliance identified by any method or means (e.g., contractor assessments, internal review processes, external assessments, employee concerns, event evaluation) that would not otherwise be reported into NTS as either a Management Issue or Occurrence, but that represent a condition of greater than low relative risk. Conditions with an associated low relative risk should not be reported. Note that a number of low risk, Severity Level II (Other-than-Serious) conditions, or both may point to the existence of a higher risk serious condition involving a programmatic problem that should be reported and addressed. Guidance on risk assessment criteria can be found at http://www.eh.doe.gov/health/rule851/851IG.pdf.

Appendix C - Program Review

Typical Agenda

Day 1

- Initial informal meeting with local DOE to provide overview of review and discuss contractor performance (1 hour).
- Entrance meeting with contractor, DOE (1/2 hour).
- Overview presentation by contractor on program implementation (1-2 hours).
- Review of selected noncompliance screening determinations for rule applicability (i.e., noncompliance determination) (1-2 hours).
- Review of selected NTS reportability determinations (1-2 hours).

Day 2

- Personnel interviews/document review (typically half day).
- DOE only pre-exit meeting (1/2 hour).
- Contractor and DOE exit meeting (1/2 hour).

Interviewees

Contractor interviewees may include the PAAA coordinator; QA manager; radiological control manager; ES&H manager; lessons learned program manager; senior management, personnel performing noncompliance screens; individuals responsible for tracking corrective actions; personnel performing QA, radiological control, or worker safety assessments; members of PAAA committees; and individuals with knowledge of specific events resulting in NTS reports.

Standard Document Request

The following documentation is typically requested in advance of a program review. This standard list may be modified based on specifics of the review or the site.

- Contractor organization chart which shows the reporting position of the PAAA coordinator, the radiological control manager, and the QA manager. Sections of site procedures identifying roles and responsibilities of these positions should be included.
- Site implementing policy and procedures addressing the following topics: noncompliance identification, screening, cause determination, NTS and internal reporting, corrective action tracking, corrective action closeout and validation, and training.
- Site procedures related to quality improvement and the corrective action process, deficiency reporting, nonconformance/quality problem resolution, injury reports.
- Summary listing (including title and status) of all site internally tracked noncompliances over the past 24 months. The listing should be sorted by year, if possible.
- Copies of logs/spreadsheets used in the initial screening of potential noncompliance issues for the 12-month period prior to request. Documentation should list title of the issue,

screening outcome, and status of corrective actions, if possible.

- Summary listing (including title and status) of all site radiological deficiency/awareness reports for the 12 month period prior to request.
- OSHA 300 log of reportable injuries and illnesses for the prior 12 months, and the most recent OSHA 300 summary report.
- Copies of any external assessments of the QA, RP, and worker safety programs conducted for the 12-month period prior to request.
- Copies of any recent contractor assessments of implementation of the program.

In addition to the above, the contractor is encouraged to provide any additional information that would provide a perspective on the implementation of the site PAAA program (i.e., annual PAAA activity report). If the information requested above is not maintained or sorted by the contractor, it should not be specifically created for this review. The contractor should instead supply the closest equivalent document.

Review Criteria

The following criteria have been developed by OE staff as a guide for the performance of program reviews. The criteria may be used (wholly or in part) during the conduct of the review. Additionally, OE staff may evaluate other areas as appropriate. Many of the following criteria may be evaluated prior to the actual onsite evaluation through the review of documentation obtained independently or through the document request.

I. General

A. Verify through discussion and document review that formally approved policy/procedures are in place to describe the program. Procedures should describe key program elements (roles and responsibilities, training, screening/reporting, trend evaluation, cause determination, tracking and completion of corrective actions, closure validation) with sufficient detail to provide for effective implementation.

B. Verify through discussion and review of organizational charts that a contractor PAAA coordinator/manager has been formally designated and has adequate authority and independence to make decisions without undue pressure from the line organization. Determine if adequate numbers of qualified support/matrix staff are available to meet program responsibilities.

C. Verify through discussion and document review that formal training has been established and is being implemented on site (may be category/target specific - general training for managers, specialized training on forms/procedures for screeners, etc.).

D. Verify through discussion that the scope of the site PAAA program is applicable to activities performed by subcontractors and suppliers, as well as principal site contractors. Ensure through review that policies and procedures reflect this scope.

II. Identification and Screening of Noncompliances

A. Verify through review that noncompliance identification/screening procedures ensure a diverse set of source documents (assessments, NCRs, ORPS, employee

concerns, external assessments, deficiency reports, safety reports, injury reports) are forwarded for screening.

B. Verify through review that procedures ensure that all applicable noncompliances are captured; noncompliances should not be screened out on the basis of inappropriate criteria. *(Note: Examples of inappropriate criteria noted to date have included ruling out noncompliances on the basis of prompt corrective action, judgment of low significance by evaluator, or that the noncompliance did not directly involve the handling of nuclear material.)*

C. Verify through interview that personnel performing initial screens of source documents are qualified (typically require subject matter experts in areas of QA, radiological controls, safety basis, worker safety) and have received training on the screening process.

D. Review screening documentation for the past year to verify that a broad spectrum of source documents is represented. Determine if input from secondary sources (i.e., subcontractor/supplier-related information) is being included.

E. Prior to site visit, independently review recent site operating experience via review of ORPS, DNFSB trip reports, etc. Evaluate for potential trends, programmatic issues, etc. Determine through onsite review whether these deficiencies were appropriately dispositioned.

F. Independently select several contractor source documents (e.g., assessment reports, deficiency reports) identifying deficiencies that represent potential noncompliances. Determine through review of screening documentation whether these source documents were formally screened and appropriately dispositioned.

G. Verify that items identified as regulatory noncompliances are forwarded for review of NTS reportability (see next section).

H. Verify that items identified as noncompliances are entered onto a formal problem resolution and tracking system to correct the noncompliance, and are identified as PAAA noncompliances on that system.

I. Review status list of non-reportable noncompliances identified by contractor over the past year for the following:

- A “reasonable” number of noncompliances were identified, based on volume of activities and number of source documents screened.
- The noncompliances reflect a mix of 10 CFR Parts 830, 835, and 851 items, and were identified through the assessment program as well as through events.
- Corrective actions are completed on schedule, with appropriate follow-up if not completed.

J. Review selected ORPS and deficiency report items that were judged not to be noncompliances to evaluate contractor judgment process.

III. Evaluation for Reportability

A. Verify through review that procedures used to describe/control the process of evaluating identified noncompliances for NTS reportability include the following:

- Identification/designation of individuals with responsibilities for evaluation for reportability, approval, and NTS report generation.
- Formal process to be used for reportability determination, with documentation of results. Specific evaluation

criteria/thresholds should be included in the procedure.

- Methodology used for evaluating potential repetitive or programmatic noncompliances.

B. Verify through interview that individual(s) making final determination on NTS reportability are qualified and have received appropriate training.

C. Verify reportability threshold criteria and reporting timeframes contained in procedure(s) are consistent with OE guidance. Also verify that procedures do not provide for the screening-out of reportable noncompliances through use of inappropriate criteria (see II.B above).

D. Review status list of NTS non-reportable noncompliances identified by contractor over the past year for the following:

- Observable trends and/or potential programmatic noncompliances are appropriately recognized and reported by the contractor.
- For selected noncompliances of apparent significance, review judgment process that was used by the contractor to determine NTS non-reportability.
- Evaluate the ratio of total number of NTS non-reportable/reportable noncompliances. *(Note: Although ratios will vary, one would expect the number of NTS non-reportables to be greater than reportables, particularly at sites with a well-functioning assessment program.)*
- Review documentation for several recent instances in which noncompliances were evaluated as requiring NTS reportability. Determine if the decision process was performed in accordance with procedure, if the conclusion was appropriate, and if NTS reporting was timely, generally within 20 calendar days after determining a noncompliance condition exists.
- Review the process used by the contractor to evaluate PAAA noncompliances for repetitiveness. Ensure appropriate timeframes are used to make this judgment. *(Note: At one reviewed site, contractor procedures required an annual review for trending/repetitiveness. This timeframe did not provide for effective and timely identification of recurring deficiencies. More commonly, sites review each noncompliance as they occur against previous occurrences - a "rolling window.")*

E. Determine whether program performance indicator data (number of NTS reportable noncompliances, total number of noncompliances, etc.) is maintained and routinely reported to senior management.

IV. Cause Determination/Corrective Action Closure

A. Verify through review that contractor procedures include/require the following elements relative to corrective action development, tracking, and closure:

- Identified noncompliances and associated corrective actions are formally tracked.
- Significant noncompliances are evaluated by formal causal analysis. Corrective actions are developed and implemented in a timely manner.
- Validation/verification of completion of corrective actions takes place for significant noncompliances prior to closure.
- Effectiveness reviews of corrective actions are conducted for significant noncompliances.

B. Review documentation for selected NTS reportable noncompliances to ensure the following:
   - A formal investigation/causal analysis is performed in a timely manner (generally within 45 days of determining a noncompliance exists).
   - Developed corrective actions correlate to causes identified through analysis.
   - For repetitive noncompliances, the causal analysis for the more recent noncompliance takes into account earlier noncompliances, corrective actions, and their efficacy.
   - NTS report and corrective actions provided input into site lessons-learned process, as appropriate.
   - Actions actually taken to close a corrective action are the same as those committed to in the original action.
   - Verification process for corrective actions was effectively implemented in accordance with procedures.

C. Review summary of corrective action closure status for identified noncompliances and any related databases (deficiency reports, ES&H assessments, etc.) to determine if contractor is completing actions within committed milestone dates.

V. Assessments/Quality Improvement

A. Pre-site visit: Review requested assessments for overall adequacy, clarity of findings, etc.

B. Verify that identified assessment findings are reviewed for applicability and NTS reportability. Independently select several significant assessment findings and crosscheck them against screening/evaluation documentation to verify they were appropriately reviewed.

C. Compare OE PAAA review findings with the results of contractor assessments of this area. Discuss differences with appropriate staff (PAAA coordinator, lead auditor, etc.).

D. review actions taken by the contractor to improve assessment processes in the past two years.

VI. Other Evaluations

A. OE may obtain information related to selected occurrences to understand their significance and compliance issues associated with for those events.

B. OE may also conduct a limited records review of worker safety issues.

C. OE may also conduct limited worker safety workplace walk-throughs as part of the program review.

D. OE may also chose to evaluate other information related to compliance for selected topical areas within Parts 830, 835, and 851.

Desktop Review of Smaller Contractors

I. Typical Information Request

A. Provide a listing of your facilities and activities that are subject to the requirements of (1) Part 835, (2) Part 830 (subpart A), and (3) Part 830 (subpart B). A brief characterization of the activities conducted at each would be helpful. (For any that are defense-related do not include classified or sensitive information.)

B. Identify your coordinator for noncompliance matters, and provide a contact phone number and email address.

C. Provide your policies and procedures that implement your noncompliance identification, screening, NTS and internal reporting, and corrective action resolution processes; or provide a description of the portions of this that are not controlled by a formal procedure.

D. Provide your policies and procedures that implement management and independent assessment programs required by 10 CFR Part 830; or provide a description of those processes.

E. Provide copies of logs/spreadsheets used in the screening of deficiencies (including title/subject) over the past 12 months that determined whether these were (1) noncompliances, and (2) reportable into NTS.

F. Provide a copy of your OSHA log of injuries and illnesses over the past 12 months, and your most recent OSHA 300 summary report.

G. Provide a summary listing (including title/subject and status of resolution) of all site internally-tracked noncompliances over the past 12 months that were determined to be below the NTS reporting threshold.

II. Review Criteria/Plan

A. Verify (ensure) the contractor has designated a PAAA coordinator. (Add this to list of coordinators if not already shown.)

B. PAAA Screening/Reporting Procedure:

- Verify the contractor has a procedure to ensure a consistent screening of potential noncompliances.
- Verify the typical quality problem sources are screened (RP deficiencies, quality deficiencies, assessment findings if different from other sources).
- Verify the procedure does not introduce inappropriate criteria to exclude issues from applicability or NTS reportability.
- Verify the procedure calls for non-NTS noncompliance issues to be tracked internally, identified as such, and managed to closure.
- Verify the timeline requirements in the procedure are consistent with OE guidance for timely decisions.

C. Logs of issues screened for noncompliance applicability:

- Verify that the set of issues represent substantive problems, and include matters from assessments, programmatic problems, and worker/supervisor/manager observations in addition to matters from events.
- Briefly review a few of these screens to make sure inappropriate criteria are not being used generally to screen out from PAAA applicability.
- Check ORPS for an example or two of matters that should have been screened, and confirm these were screened.
- Identify examples that may have been screened inappropriately.

D. Logs of noncompliance issues screened-out from NTS reportability:

- Check a few of these screens to make sure inappropriate criteria are not being used generally to screen out from

NTS reportability.

- Identify examples that may have been screened incorrectly.
- Check set of NTS reports over past year for this contractor (if any) to confirm proper decisions made on reportability, and that issues were comprehensively investigated/evaluated (RCA, etc.) and that appropriate and timely actions were being taken.

E. Internally tracked noncompliance issues:

- Check the set of these to make sure it is a reasonably large set for the type of operations conducted, and the set includes a reasonable mix of QA, RP, and safety basis issues.
- Confirm these are identified as nonreportable noncompliances and tracked to closure.
- Confirm for several examples that closure appears to be timely.

Appendix D - Enforcement of Internal Dosimetry

This appendix clarifies OE's position on 10 CFR Part 835 requirements related to monitoring for internal exposure. Specific areas addressed include:

- Prospective determination of employees that are "likely to receive" 100 millirem or greater per Part 835.402, *Individual Monitoring*.
- Application of enforcement policy in taking credit for respiratory protection in prospective determinations.
- Use of contractor's policies regarding personnel internal exposure to radioactive material.
- As Low As Reasonably Achievable (ALARA) programs.
- Clarification of enforcement with regard to internal dosimetry programs.

Prospective Determination of Employees "Likely to Receive" 100 mrem or More

It is important that contractors perform a prospective determination to identify radiological workers who are required to be monitored by Part 835.402(c), i.e., those workers likely to receive 100 mrem or more from all occupational radionuclide intakes in a year. Contractors should establish and document a clear basis for the prospective determination as part of the contractor's existing internal dosimetry program and/or technical basis documents. Such documents should include the technical rationale used by the contractor for including or excluding populations of radiological workers from monitoring for internal deposition of radioactive materials. Contractors should maintain these documents as part of the contractor's record system. However, if the contractor does not adequately document the basis for identifying the radiological worker population that is required to participate in the internal dosimetry program, then, for compliance purposes, all workers participating in the internal dosimetry program will be considered likely to receive 100 mrem or more in a year and it will be assumed that they are being monitored in accordance with Part 835.402.

It should be recognized that changes in a facility's operations or operational status can and do occur, particularly in the area of decommissioning and decontamination activities in which previously contained radioactive materials systems are opened and accessed by workers. These operational changes would then require reconsideration of the working conditions and modification of the determination of the "likely" exposed population of radiological workers when performing a prospective determination of employees likely to receive 100 mrem or more in a year. Contractors should also continually reassess the determination when initiating operations that are infrequently performed.

As with all safety programs implemented by the DOE contractor community, the technical bases, decisions, and implementation of the safety programs at various sites will continue to be subject to DOE review and evaluation. A contractor's determination that a population of workers does not require monitoring under Part 835.402 does not automatically result in the monitoring (or lack of monitoring) of those individuals being outside DOE's purview. As a result of DOE's review, differences in professional

opinion may arise or new factors and considerations may result in the need to reassess prior conclusions. As always, DOE will work to resolve any differences. However, no programs, decisions, or bases supporting the determination of the population of workers required to be monitored under Part 835.402 will be considered outside DOE's continued purview.

Application of Enforcement Policy in Taking Credit for Respiratory Protection in Prospective Determinations

In work situations in which a contractor is considering the use of respiratory protection in performing prospective exposure estimates to identify those individuals who require internal exposure monitoring per Part 835.402, credit for respiratory protection may be allowable in certain circumstances. For enforcement purposes, credit for respiratory protection may be considered provided that the contractor has well planned and controlled work activities, timely and accurate monitoring of work areas, a demonstrable history of implementing effective work controls, and a respiratory protection program that meets the applicable Part 851 requirements (specifically 29 CFR Part 1910.134(c) and ANSI Z88.2 (1969)). Credit for respiratory protection should not be taken, however, for situations in which potential airborne radiological releases are not highly predictable or controllable. Examples of such situations include facilities with multiple release points, unidentified or chronic releases, or instances of airborne release not closely associated with planned work activities. The contractor's analysis of the effectiveness of the site's respiratory protection program and documented position in taking credit for respiratory protection is but one aspect of the overall prospective determination and is, therefore, subject to OE review.

Use of Contractor Policies regarding Personnel Exposures to Radioactive Material

Some contractors may voluntarily establish policies that do not permit any intakes of radioactive material or that limit intakes of radioactive material to less than 100 mrem from all occupational intakes in one year. Such a policy by itself, however, is not sufficient to conclude that a routine bioassay program at such facilities would not be required. Policy implementation through detailed work control and internal dosimetry documents that ensure compliance with Part 835.402 would be required.

Additionally, the contractor at a site should have a documented technical basis that identifies known working conditions in the various facilities and a history of low internal exposures for the site's radiological workers. As discussed above, changes in a facility's operations or operational status can and do occur, particularly in the area of decommissioning and decontamination activities where previously "sealed or contained" systems are opened and accessed by the workers. These operational changes would then require reconsideration of the working conditions and the potentially radiologically exposed working population.

As Low As Reasonably Achievable Programs

ALARA is not a numerical value or dose level but rather a process which has as its goal the objective of maintaining doses as low as is reasonably achievable. Consequently, the monitoring level of 100 mrem established by Part 835.402(c)(1) does not define a threshold value for ALARA or for enforcement considerations.

Clarification of Enforcement with Regard to Internal Dosimetry Programs

Some contractors have chosen, at their discretion, to extend bioassay monitoring programs to include individuals not meeting the "likely" criteria contained in Part 835.402(c)(1). Contractors may perform such discretionary monitoring for a variety of reasons, such as meeting union commitments or as a program quality control measure.

OE views the following specific elements of a discretionary monitoring program as falling within Price-Anderson regulatory space. They are consequently subject to review and potential enforcement.

- The contractor's prospective analysis, determination, and supporting rationale for identifying the worker population that is not "likely to receive" 100 mrem.
- The contractor's mechanisms for timely, continuing analysis, and feedback from the results of the discretionary bioassay program. Positive bioassay results or trends may indicate that individuals within the "discretionary" population require re-evaluation and actually fall under the monitoring requirements of Part 835.402 in that these individuals may be likely to receive 100 mrem in one year.
- The contractor's mechanism for recording the dose results from discretionary monitoring in accordance with Part 835.702.

Additionally, a failure of the discretionary monitoring program may indicate a similar failure of the mandatory program. Moreover, if a contractor operates its discretionary and mandatory bioassay programs together as a unified program, a failure of the discretionary program may correlate to a systemic failure in the entire program and would require evaluation by OE. Therefore, a failure in the discretionary program may demonstrate a pattern of noncompliance in the mandatory bioassay program required by Part 835.402(c).

In general, instances of procedural noncompliance related directly to the discretionary monitoring aspects of the bioassay program would fall outside the constraints of Part 835.402 and would not be subject to DOE enforcement unless there was a significant breakdown that has the potential to affect compliance with the general requirements of Part 835.401. In light of the above, the contractor is cautioned, however, not to reduce overall emphasis on bioassay procedure compliance. Attempts to implement a graded procedural compliance based on perceived regulatory significance may serve to confuse and send an inappropriate message to the workforce. OE will make a determination whether regulatory violations occurred with respect to the discretionary bioassay program on a case by case basis, taking into account the commitments established in the Radiation Protection Program for Part 835 and in the Quality Assurance Program for Part 830.121.

Appendix E - 10 CFR Part 851 References to Forthcoming Guidance and Enforcement Program Plan Cross-Reference

10 CFR 851 Section	Topic	Program Plan Guidance
Preamble at Page 6866	Multiple employer worksites – Prime's liability for violations by another DOE-contractor	Chapter VIII, p. 54, *Multiple Employer Worksite*
Preamble at Page 6866	Voluntary Reporting Thresholds	Chapter IV, p. 14, *NTS Reporting*, and appendix B
Preamble at Page 6874	NTS Reporting Thresholds	Chapter IV, p. 14, *NTS Reporting*, and appendix B
Preamble at Page 6874	Employee Misconduct	Chapter VIII, p. 56, *Employee Misconduct*
Preamble at Page 6874	Possible citation of Prime for subcontractor violation	Chapter VIII, p.50, *Suppliers and Subcontractors*, and p. 54, *Multiple Employer Worksite*
Preamble at Page 6875	Enforcement policy for subcontractor violations	Chapter VIII, p.50, *Suppliers and Subcontractors*, and p. 54, *Multiple Employer Worksite*
Preamble at Page 6877	Enforcement actions involving both nuclear and worker safety, and limits on combined penalties	Chapter VIII, p. 53, *Nuclear Safety and Worker Safety and Health Noncompliances*
Preamble at Page 6878	General Duty Clause	Chapter VIII, p. 55, *General Duty Clause*
Preamble at Page 6879	Terminology "free from hazards" in General Duty Clause	Chapter VIII, p. 55, *General Duty Clause*
Preamble at Page 6882	Multi-employer worksites – Prime liability for violations by another DOE-contractor	Chapter VIII, p. 54, *Multiple Employer Worksite*
Preamble at Page 6883	Multi-employer worksites – Prime's liability for subcontractor violations	Chapter VIII, p.50, *Suppliers and Subcontractors*, and p. 54, *Multiple Employer Worksite*
Preamble at Page 6896	Use of National Consensus Standards	Need for any enforcement guidance is to be determined after EH-52 prepares guidance on open issues in this area.
Preamble at Page 6904	Guidance on screening of violations, enforcement process, and appeals process	Program Plan in general, and chapters V, VI, and VII in particular.
Preamble at Page 6904	NTS Reporting Thresholds	Chapter IV, p. 14, *NTS Reporting*, and appendix B
Preamble at Page 6904	Affirmative defenses for enforcement proceedings.	Guidance is addressed in this Program Plan on attributes that are considered and credited in investigation activities, applying enforcement discretion, structuring enforcement actions, and mitigation considerations.

Preamble at Page 6905	Inspection protocols	Refer to chapters I – VII of this Program Plan for guidance on the enforcement process, and chapter VI in particular on investigation and focused inspection activities.
Preamble at Page 6905	NTS reporting thresholds	Chapter IV, p. 14, *NTS Reporting*, and appendix B
Preamble at Page 6910	Unpreventable employee misconduct	Chapter VIII, p. 56, *Employee Misconduct*
Preamble at Page 6924	Enforcement against Subcontractors and Suppliers	Chapter VIII, p.50, *Suppliers and Subcontractors*, and p. 54, *Multiple Employer Worksite*
Preamble at Page 6927	Unpreventable employee misconduct	Chapter VIII, p. 56, *Employee Misconduct*
Preamble at Page 6928	Enforcement philosophy on contractor self-reporting, NTS reporting process, thresholds	Chapters II, III, IV, and appendix B
Preamble at Page 6928	Coordination of DOE reporting processes	Chapter IV, p. 11, *Contractor Screening Processes*

Appendix F - Contractor Investigation, Causal Analysis, and Corrective Action

As part of the investigation of potential nuclear safety noncompliances, OE has routinely reviewed the contractor's investigation of the noncompliance, the associated causal analysis, and the corrective actions developed by the contractor to resolve the noncompliance and prevent recurrence. In the process of those reviews OE has noted several common deficiencies. Additionally, many of the enforcement actions undertaken by OE involve recurrent events or deficiencies, indicating weaknesses in contractor processes to develop and implement effective corrective actions. In response, OE has chosen to provide additional information regarding observed deficiencies as potential lessons-learned for the DOE contractor community.

It should be noted that OE believes that the following lessons learned information is also applicable to worker safety, even though the observations to date are the result of nuclear safety enforcement experience. This is because contractor investigation, casual analysis, and corrective action processes are typically institutional in nature and cover both worker and nuclear safety functional areas as they relate to managing events and deficiency resolution.

I. Investigation, Causal Analysis, and Corrective Action Process

A. Relevant Requirements and Other Regulatory Drivers

Specifically for nuclear safety, Part 830.122(c), criterion 3-*Management/Quality Improvement*, establishes DOE requirements for the investigation of identified nuclear safety deficiencies, the determination of underlying causes, and the development and implementation of effective corrective actions to both correct the deficiency and prevent recurrence. Additionally Part 820, appendix A, *Nuclear Safety Enforcement Policy*, delineates incentives for contractor timely and comprehensive corrective actions for noncompliances, including application of discretion and/or mitigation.

Although, the worker safety rule does not mandate a quality improvement process, the enforcement provisions of Part 851, and its Enforcement Policy in appendix B, establish regulatory drivers through crediting contractor timely and comprehensive corrective actions as one of the factors in applying enforcement discretion and possible mitigation. The preamble to Part 851 also notes that for contractor violations indicative of egregious and/or general performance failures (that may be manifested by recurrent deficiencies and violations), application of contract penalties may be appropriate.

The general deficiencies OE has noted in its investigation activities and the observation of various recurring problems and repetitive events are not consistent with concluding compliance with the QA Rule requirements or support an ability to grant discretion or mitigation as delineated in the above enforcement policies. It is hoped that contractors will evaluate and improve their processes in these areas and avoid the types of deficiencies OE has noted as reflected in this guidance. It should be noted that the information presented is not intended to establish new requirements nor serve as a comprehensive guide on the

methodology or approach for the performance of causal analysis or corrective action management. A variety of such general program guidance has already been developed by the Department[7] and other industry groups such as the Institute for Nuclear Power Operations (INPO). The following areas are highlighted due to the common deficiencies observed in these areas.

B. Discussion

OE's general expectation is that a contractor conducting an investigation/causal analysis will ensure that personnel conducting the investigation are adequately trained and qualified, that the investigation includes appropriate scope and depth, and that corrective actions are timely and clearly relate to identified causes. This expectation applies both to contractor investigations of events and to investigations of safety issues identified as a result of more proactive means (e.g., assessments).

Consistent with Part 830.7, OE recognizes that the level and effort of the contractor investigation and corrective actions should be commensurate with the significance and complexity of the problem, i.e., a graded-approach should be applied. As an example, identification of apparent causes may be an appropriate endpoint when investigating less significant problems, while the conduct of a root cause analysis would be appropriate for more significant or complex issues. As one point of reference, OE has noted that many contractors use the criterion of NTS reportability as one of several thresholds for determining whether a root cause analysis (rather than the less rigorous apparent cause analysis) will be performed.

C. Scope of Investigation

Once a deficiency or quality problem has been identified, it must be fully evaluated and characterized so that it may be effectively corrected. As part of its review of a contractor's investigation of a nuclear or worker safety problem, OE typically questions whether the investigation included the following elements:

- Extent of condition review.
- Precursor or historical review (including effectiveness of prior corrective actions).
- Evaluation of assessment performance.

1. Extent of Condition Review

Once a significant quality problem has been identified, a review should be performed to determine the full extent and generic implications of the problem. This includes determining whether the same problem/condition exists elsewhere (i.e., transportability of condition); and whether the same root or underlying causes of the problem/condition may be affecting performance in other applications (transportability of cause). Such a review may be termed an extent of condition (EOC) review. Areas to be covered as part of an effective EOC review will vary with the specifics of the identified problem, but generally include the following:

[7] See DOE G 414.1-2A, *Quality Assurance Management System Guide for use with 10 CFR 830.120 and DOE O 414.1*; DOE-NE-STD-1004-92, *Root Cause Analysis Guidance Document;* DOE 231.1-2, *Occurrence Reporting Causal Analysis Guide*; DOE G 225.1A-1, *Implementation Guide for use with DOE O 275.1, Accident Investigation*.

- Looking for the same problem in applications, locations or facilities other than where originally found;
- Looking for other manifestations of the identified root or underlying causes of the problem;
- Looking for similar or related problems, or problems that can be anticipated based on the identified problem;
- Reviewing prior applications of the deficient process or procedure to see if earlier deficiencies had gone unnoticed.

The approach used in conducting an EOC review may also vary based on the details and significance of the identified problem (i.e., a graded approach). Typically, a series of focused field observations or assessments in conjunction with document reviews are performed; it is unlikely that a simple review of site trending data or quality problem tracking systems will provide the specificity needed to adequately assess the scope of the problem.

The most frequently observed performance deficiency in this area is the simple failure to do an EOC review for deficiencies with a clear potential generic applicability. OE has also noted instances in which contractors have conducted event database searches for similar prior events or for general negative performance trends, and have termed these reviews "extent of condition" reviews. Although OE understands such database reviews have value (see following precursor review section), they do not constitute an effective EOC review. Inappropriate use of this terminology may provide senior management a false confidence that an identified problem is limited in scope.

2. Precursor/Historical Review

A contractor's investigation and analysis of an identified quality problem should also include a precursor or historical review to determine if the same or similar problem has occurred previously. In making this determination, it is appropriate to look at both the problem condition and underlying causes to determine if the problem is recurrent. If a quality problem is determined to be recurrent, the contractor's analysis should include an evaluation to determine why prior corrective actions were not effective in preventing the recurrence of the problem. The results of that evaluation should be factored into the development of corrective actions for the current event or problem. Unlike an EOC review, a precursor or historical review is retrospective in nature and can usually be effectively conducted using site database information on events, assessment results, etc.

3. Evaluation of Assessment Performance

Over the past two years, OE has increasingly focused on the implementation and effectiveness of a contractor's assessment programs in improving nuclear safety performance. OE has concluded that the self-identification of nuclear safety deficiencies through implementation of an effective internal assessment program (rather than by reacting to events) represents a cost-effective method of improving nuclear safety performance, and that contractors should strive towards implementing an assessment-driven (vice event-driven) nuclear safety program.

Consistent with the above, during the conduct of an event investigation OE typically questions whether the subject

nuclear safety noncompliance should have reasonably been identified through implementation of the contractor's assessment program. Based on the initial answers, follow-up questions can lead to the identification of deficiencies in assessment scheduling, quality, or corrective action development and implementation. OE recommends that, where appropriate, contractors perform a similar evaluation as part of their investigation of an event or other nuclear safety problem.

D. Causal Analysis

The conduct of an effective causal analysis is an essential step in developing appropriate corrective actions for an identified nuclear safety quality problem. Numerous causal analysis techniques and methodologies are currently being utilized by the DOE contractor community. OE has no preference assuming each is used in an appropriate fashion by trained and qualified personnel.

1. Depth of Analysis

The depth of the contractor's causal analysis should reflect the significance and complexity of the nuclear safety quality problem or event under analysis. Some problems may be easily understood, while others may require considerable in-depth analysis.

Based on review of a large number of contractor causal analyses, OE considers the most frequent deficiency in this area to be the tendency for analyses to truncate before getting to underlying issues, i.e., they do not go "deep" enough. In particular, OE has found that contractors frequently conclude the analysis at some failure condition (e.g., failure to follow procedures, inadequate training, inadequate administrative controls) and then identify this condition as the root or underlying cause. Although convenient for binning and trending purposes, these failure conditions often do not represent satisfactory endpoints. A more detailed causal analysis should go further and ask why the procedure was not followed, why the training was inadequate, or why there was an inadequate administrative control.

2. Cultural/Organizational Factors

The endpoint of "worker failure to follow procedures" has been frequently cited as an underlying cause in contractor causal analyses, and corrective actions have consequently been focused on retraining or disciplining the worker or revising the procedure or process. Although such actions may be appropriate in some cases, contractors should also evaluate organizational and management issues for any contribution to the failure. A variety of cultural or organizational factors may underlie worker procedural compliance issues, and can include the following:

- Perceived differences in management's actions versus their words;
- Local supervisory influences contrary to management's stated expectations;
- Emphasis on production or schedule;
- Inconsistent standards applied across the institution;
- Long-standing organizational practices conflicting with procedures and becoming the default process;

- Examples set by fellow workers;
- Desire for a successful experiment or evolution.

A comprehensive investigation of a nuclear safety problem should attempt to identify all the particular influences that are causing the problem, including the management or supervisory influences that affect workers' behaviors. OE recognizes these underlying factors are potentially difficult to identify or "get to" in an investigation, and may require a senior level effort, special expertise, or a number of one-on-one interviews.

3. Breadth of Analysis

An additional concern noted by OE is that some causal analyses simply do not identify all significant issues associated with an event. For example, OE is typically just as interested in the reasons why a long-standing nuclear safety noncompliance persisted without identification as to the specific causes of the original noncompliance. Questions such as these are generally not asked as part of the causal analysis, which tends to focus on the specific failure condition.

E. Corrective Actions

OE evaluates contractor Corrective Action Plans (CAP) as part of the routine review of submitted NTS reports during the conduct of PAAA program reviews and as part of an investigation into a nuclear safety problem. As part of its review, OE uses the general criteria outlined below to evaluate corrective actions. OE also relies on the judgment of cognizant DOE/NNSA representatives when evaluating the adequacy of contractor corrective actions:

- Clear linkage to causal analysis – OE's review includes identifying whether the contractor has developed corrective actions for all root and significant contributing/underlying causes identified through the causal analysis process.
- Appropriateness of corrective actions – OE's review includes verifying that stated corrective actions make sense and appear appropriate for the problem being addressed (i.e., behavioral or culture issues are not being addressed by a procedure revision) and that deliverables are clearly stated and achievable.
- Timeliness of corrective actions – OE's review includes verifying that schedules for corrective action completion reflect an appropriate priority and do not extend out past a reasonable timeframe. OE expects that any delays in corrective action completion will be justifiable and limited in number and extent.
- Verification of effectiveness – OE's review includes determining whether the contractor has included an effectiveness verification (described below) as a planned corrective action for significant or complex nuclear safety problems.

Several contractors have implemented the practice of conducting an "effectiveness verification" as a corrective action for a significant nuclear safety issue. This verification, typically performed several months after completion of the other corrective actions, is intended to assess workplace performance in the subject area and to determine whether the corrective actions have been effective. Effectiveness verifications can also be performed as an element of the independent assessment process.

OE views the practice of conducting verification assessments as a positive one, which should reduce the incidence of recurrent events. For nuclear safety noncompliances reported to the NTS, it is the contractor's option whether the planned verification assessment is formally listed as one of the NTS report's corrective actions (which may involve keeping the NTS report open for a longer period of time) or whether it is tracked separately. It should be noted that the implementation of a verification assessment approach does not alter OE's expectation of a verification of completion of the proposed corrective actions by the contractor and local DOE personnel before closing an NTS report.

II. Case Examples

To observe some of the specific deficiencies in this area associated with various enforcement cases, one may look at several areas from the OE website:

- In looking at each of the cases where enforcement action was taken, those cases that cite the QA rule *Quality Improvement* section generally involve conditions where inadequate steps had been taken in the investigation, causal analysis, and/or corrective action area.
- The transmittal letter for enforcement action cases may identify deficiencies in the investigation, causal analysis, and/or corrective action area, and also may have impacted considerations of mitigation.
- The transmittal letter or the PNOV may note problems with the recurring nature of the event or underlying problems, thus indicating deficiencies in the contractor's investigation, causal analysis, and corrective action area.
- Program review reports may also note deficiencies in corrective action processes.

Appendix G - Contractor Assessment Program Weaknesses

Background

10 CFR Part 830.121(a) requires that contractors conducting activities that affect, or may affect, the nuclear safety of DOE nuclear facilities must conduct work in accordance with the Quality Assurance (QA) criteria in Part 830.122. Part 830.122(i) identifies criteria specific to the conduct of management assessments. Part 830.122(j) identifies criteria relative to the conduct of independent assessments. Both assessment functions are required but, where appropriate, must be implemented in a graded-approach fashion consistent with Part 830.7. Additionally, in the worker safety area, failure to discover problems such as through an effective assessment process can lead to loss of mitigation in an enforcement action.

Supplemental DOE guidance specific to assessments has been provided in DOE G 414.1-1A, *Management Assessment and Independent Assessment Guide*. DOE G 414.1-1A provides significant detail and guidance on assessment program purpose, objectives, and implementation. In addition, the Energy Facility Contractors Group (EFCOG) has issued an assessment guide entitled *Implementing the Assessment Process at the Department of Energy Facilities.* This guide describes the types of assessments, steps in the assessment process, obstacles in implementing an effective assessment program, and ways to overcome these obstacles. The EFCOG assessment guide can be accessed at http://efcog.org/wg/paaa/documents.htm.

When conducted effectively, contractor assessment activities serve as part of a significant performance feedback loop, allowing for the proactive identification and correction of safety deficiencies that might otherwise result in significant events. DOE enforcement activities over the past several years, however, have indicated the need for improvement in the conduct of contractor assessment programs. The following general concerns have been identified:

- A lack of assessment activity in significant safety related areas.
- Ineffective assessments, as evidenced by the absence of assessment findings in areas in which programmatic problems have been disclosed through other means (e.g., operational history, events).
- Weaknesses in the effective correction and closure of assessment issues, with resulting recurrent and long-standing deficiencies.

During investigations of potential PAAA noncompliances, OE typically reviews contractor assessment performance and results as they specifically relate to the subject area of the investigation. OE will continue its emphasis on evaluating the implementation of contractor assessment programs as described in the Implementation section below. In addition, OE will seek to measure, through the use of PAAA program reviews, contractor performance in transitioning to an assessment-driven culture by focusing on contractor assessment initiatives aimed at improving their ability to proactively identify conditions adverse to quality. The emphasis here is on continuous assessment process improvement and not on contractor “binning” of PAAA noncompliances to demonstrate reaching of a numerical

percentage.

Management and Independent Assessment (M&IA) Programs Review Criteria

M&IA review criteria are provided in the following sections. OE intends to use the review criteria as an internal guide during evaluations of contractor assessment program implementation, to promote consistency of OE review activities. The M&IA review criteria largely reflect relevant Part 830.122 requirements, logical extensions of those requirements, or the evaluation of contractor performance against their applicable procedures. The criteria do not reflect supplemental DOE or external guidance relative to M&IA programs, and OE will not be using such supplemental or external guidance to evaluate contractor programs except as it is incorporated into contractor Quality Assurance program (QAP) documentation. This evaluation approach merely reflects OE's regulatory perspective, however, and should not be viewed as encouragement to contractors to down scope their programs.

Implementation

OE will increase the level of emphasis it directs towards the evaluation of contractor assessment program compliance through the following means:

- Broadening the scope of routine noncompliance investigations to include increased evaluation and follow-up of contractor assessment program deficiencies,
- Continued monitoring of contractor reporting information with increased attention to assessment- or corrective action-related items,
- As necessary, the conduct of contractor M&IA program compliance reviews (in response to negative performance indicators or DOE request),
- Review NTS database to evaluate progress in shifting from an event-driven to an assessment driven culture, and
- Determine to what extent specific assessment program improvement initiatives have been undertaken to drive assessment program improvement.

Consistent with the Part 830 scope and OE's jurisdictional authority, OE review activities will be directed towards evaluating compliance of contractor M&IA program activities with Part 830.122 M&IA nuclear safety requirements for those facilities and activities subject to the requirements. Enforcement of identified noncompliances will be pursued as appropriate, consistent with the specifics of the noncompliance and in full consideration of any mitigating factors.

The review criteria will be used as an aid to promote consistency and are not intended to represent new or supplemental requirements. Evaluations of contractor compliance performed by OE will be made directly against applicable Part 830 criteria, the contractor's documented QAP, and associated policies and procedures.

The following criteria have been developed to support OE evaluations of contractor implementation of the M&IA requirements of Part 830.122. These review criteria are intended to improve the consistency of OE reviews and do not represent new or additional requirements in the M&IA area. Sections I-III contain general programmatic criteria which may be utilized during any review; section IV contains more focused criteria and

is intended for use (along with applicable general criteria from sections I-III) during an OE investigation of a specific event or noncompliance.

The contractor's documented QAP describes how the contractor will satisfy Part 830.122 quality assurance criteria consistent with the graded approach provisions of Part 830.7. The following review criteria should consequently be reviewed and adjusted as necessary to reflect the specific commitments and provisions described in the subject contractor QAP.

I. Programs and Procedures

A. Verify that the contractor's QAP document(s) describes how the contractor is meeting the M&IA criteria of Part 830.122. Review to determine that the QAP description reflects current conditions, referenced procedures are correct, etc.

B. Verify that the contractor's management assessment (MA) and independent assessment (IA) processes are adequately described in approved procedures or instructions. Determine if the procedures adequately address the following:

- organizational responsibilities;
- assessment prioritization, planning and methodology;
- training/qualification requirements;
- reporting and records; and
- assessment follow-up actions.

C. Also verify that the contractor's quality problem resolution/corrective action process is described in formal procedures. Determine if the procedures adequately address the following:

- organizational responsibilities,
- problem/deficiency significance evaluation,
- responsibilities and criteria for conducting causal determinations,
- corrective action development and approval,
- documentation of disposition and resolution,
- corrective action closeout, and
- verification of effectiveness.

D. Verify that the group responsible for performing IAs is reasonably and obviously independent from and has no direct responsibility for the work being assessed. Also verify that the IA group has been assigned appropriate authority to perform their assessment function.

E. Verify that a process has been established to ensure that IA assessors are appropriately trained and qualified and knowledgeable in the areas to be assessed.

F. Verify that the MA program/procedures require the direct participation of management-level individuals in the conduct of MAs (unless defined differently in contractor procedures, "management-level" or "management" includes second-level supervision and higher). In evaluating level of management involvement, note that specific support activities (e.g., data collection) may be delegated to staff. It is anticipated, however, that managers will be directly involved in the process and that the resulting MAs will represent the

evaluation and conclusions of management.

G. Verify contractor progress in shifting from an event-driven to an assessment driven culture.

H. Verify to what extent specific assessment program improvement initiatives have been undertaken to drive assessment program improvement.

II. Implementation – Management Assessments (MA)

A. Select at least two MA assessment units (e.g., facilities, operational divisions, etc.) and review the current MA schedule and completion status. Verify that procedural expectations for scope and scheduling are being met and that management processes are being assessed. For assessments that were not completed, evaluate reasons/factors for not completing them.

B. Select examples of completed MAs for detailed review. Review should include the assessment report, supporting documentation as necessary, any associated corrective action plan, and selected corrective action closure documentation. Determine the following:

- Verify that the assessment was planned, conducted, and reported in accordance with procedural requirements.
- Verify through review and interview that management was involved in the completion of the assessment (involvement may include participation in the data collection or evaluation of results).
- Verify that personnel performing the assessment were trained in the assessment process and knowledgeable of the program, system, or process being assessed.
- Verify that quality problems identified during the assessment were evaluated and that significant problems were entered into a formal corrective action system consistent with site procedures.
- Review causal analyses and corrective actions associated with significant assessment findings. Verify that causal analyses evaluate extent of conditions and that corrective actions address causes and appear appropriate to prevent recurrence.
- Verify that corrective actions are assigned to specific "owners," have associated milestone dates, and are being completed/closed in a timely fashion.
- Review closure documentation for selected corrective actions to verify that completed actions are consistent with planned actions. Determine if adequate evidence exists to support closure.

C. Review additional sources of performance information (e.g., prior or subsequent MAs, external assessments, and occurrence reports) for one of the assessment units discussed in item II.B above. Determine if subject MA results are consistent with other indicators of performance and if findings identified during the subject MA represent long-standing or recurring problems.

D. Review MA program documentation to determine whether the contractor has included methods in addition to assessments (e.g., event review, performance indicators, etc.,) in its overall MA strategy. In such instances, evaluate and determine the

following for one of the assessment units discussed in II.B above through personnel interview and review of selected documentation:

- that MA methods are consistent with applicable procedures, and
- that identified quality problems are being appropriately tracked, controlled, and resolved consistent with procedures.

E. Based on interview with management representatives and review of MA results (from II.B above), evaluate the effectiveness of the MA process in identifying and correcting problems that hinder the organization from achieving its objectives.

III. Implementation – Independent Assessments (IA)

A. Review the current IA schedule. Verify that procedural expectations for scope and scheduling are being met. The IA schedule should demonstrate that assessments are being performed to measure item and service quality; to measure the adequacy of work performance; and to promote improvement.

Although OE emphasis in this area should focus on evaluating performance against the contractor's procedural requirements, the OE reviewer should consider the following during review of the IA schedule:

- The scheduling process should consider factors such as risk, time since last assessment, operational activities during the assessment period, feedback from trending, events, or other assessments, etc.
- The schedule should reflect that significant facilities, operations, and functional areas are being assessed on a periodic basis.
- The IA schedule (or individual assessment scope) should reflect the observation/evaluation of work activities and practices.

B. Review completion status of the IA schedule. For scheduled assessments that were not completed, evaluate the reasons/factors for not completing.

C. Select several completed IAs for detailed review (assessments selected by the OE reviewer should reflect a mix of facilities and topic areas). Review should include the assessment report, backup assessment documentation as necessary, selected associated corrective action plans, and selected corrective action closure documentation. Determine/perform the following:

- Verify that the assessments were planned, conducted, and reported in accordance with procedural requirements.
- Verify that assessors participating in the assessments were qualified in accordance with procedures and knowledgeable in the areas being assessed.
- Verify that assessment findings (i.e., quality problems, issues) were evaluated and significant findings were entered into a formal corrective action system consistent with site procedures.
- Review causal analyses and corrective actions associated with significant assessment findings. Verify that causal

analyses evaluate extent of conditions and that corrective actions address causes and appear appropriate to prevent recurrence.

- Verify that corrective actions are assigned to specific "owners," have associated milestone dates, and are being completed/closed in a timely fashion.
- Review closure documentation for selected corrective actions to verify that completed actions are consistent with planned actions. Determine if adequate evidence exists to support closure.

D. Review additional sources of performance information (e.g., prior or subsequent IAs, external assessments, occurrence reports) for one of the assessed facilities or topic areas discussed in item III.C above. Determine if subject IA results are consistent with other indicators of performance and if findings identified during the subject IA represent long-standing or recurring problems.

E. Based on interview with IA and line management representatives and review of IA results (from III.C above), evaluate the effectiveness of the IA process in identifying quality problems and promoting improvement.

IV. Review as Part of OE Specific Investigation

As part of the investigation document request (or at onset of site investigation), request any recent (within approximately 24 months) prior assessments that evaluated performance within the subject area of the investigation. Determine/perform the following:

- Review and evaluate general adequacy of the assessments using applicable review criteria II.B or III.C.
- If prior assessments identified quality problems similar to those evident during the current investigation, determine the following through review and interview:
  - whether effective causal analyses were performed for the prior quality problems consistent with procedural requirements,
  - whether identified corrective actions for the prior quality problems were reflective of causes identified during the causal analysis and were effectively completed.
- If no prior assessments of the subject area of the investigation were performed, determine whether the contractor has been meeting procedural requirements or scope and scheduling using applicable review criteria II.A and III.A.

Appendix H - Enforcement of QA Rule Applicability

Summary of Key Requirements and Interpretive Ruling Statements

10 CFR Part 830.120 states that the quality assurance requirements of subpart A apply to contractor activities, including providing items and services that affect, or may affect, the nuclear safety of DOE nuclear facilities. In Ruling 1995-1, the DOE Office of General Counsel further clarified that the scope of the QA rule (currently subpart A), applies to all DOE activities that have the potential to cause radiological harm, in the present or future, other than those already explicitly excluded by the rule.

Part 830 does allow requirements to be applied in a graded approach, such that work that poses a more significant hazard must have a greater level of control. It does not stipulate that work posing a lesser hazard does not require compliance with subpart A requirements. An appropriate level of work controls (planning, procedural controls, etc.), training and assessment, for example, should be applied to ensure the activity is performed in a quality manner and does not adversely affect nuclear safety or materials.

Specific Applicability Issues

Attempting to limit QA requirements to safety basis facilities, equipment, and/or operations.

OE has encountered some questions and confusion concerning the relationship of Part 830 subpart A QA requirements with subpart B requirements for developing a safety basis for higher hazard facilities. In general, any language or site/facility specific requirements developed as part of or contained in existing safety basis documents cannot in and of itself further "narrow or limit" the applicability of subpart A rule requirements to only higher hazard facilities or activities.

Subpart A requirements apply to all nuclear facilities, in a graded approach, including those below the subpart B hazard category 3 threshold. Subpart B requirements, though, apply only to hazard category 1, 2 and 3 facilities. In the preamble to the 1994 QA final rule, DOE rejected comments that requested a threshold to exclude coverage of lower hazard facilities. In addition, DOE reaffirmed its intent to cover all facilities that involve radioactive material in such form and quantity that a nuclear hazard potentially exists. There have been a number of events and some enforcement cases with actual and potential radiological consequences to workers within the DOE complex that involved facilities and activities below subpart B nuclear hazard thresholds. Facilities with more limited quantities of nuclear material as well as activities such as waste handling, environmental remediation, decontamination, certainly can have the potential to cause radiological harm.

Noncompliance associated with proper work control is a common contributing cause for such events.

OE has also encountered situations involving facilities that have a rule-required safety basis but for which site QA programs were inappropriately limited to a defined set of systems, equipment, or operations described within safety basis documents (documented

safety analyses and technical safety requirements). This also is inconsistent with the scope and requirements of the rule. In general, DOE enforcement actions have involved the following: equipment/safety degradation, improper modification, maintenance, and operation of safety systems or features. However, several cases have also involved situations in which work not involving safety systems or features still had a potential nuclear safety implication, due to the location or nature of the work, or potential effects of some adverse event.

One specific example included a fire and explosion involving a canister of organic material that was left unattended in an oven. The activity did not directly involve any safety-related equipment described in the safety basis and did not involve any nuclear materials. The fire and explosion led to facility damage and had the potential for radiological harm if nuclear material had been in the area at the time of the event. Rule noncompliances associated with work control contributed to this event.

Another case involved the installation of drain sumps in a facility. The sumps were being installed to contain any fluid spills and to preclude releases that might violate environmental restrictions. The sumps were not a nuclear safety feature described in the safety basis, but were being installed in an area that contained switchgear, cabling, and power feeds for facility safety features. Further, the sump installation was not contained within the boundaries of the nuclear facility but had the potential to cause loss of power to safety equipment for a nuclear facility. Noncompliances associated with work planning and control for this activity had the potential to negatively affect the nuclear safety of this facility.

Attempting to limit QA requirements to work involving only a physical activity and/or direct handling of radiological material.

In its reviews, OE has found certain contractors who considered Part 830, subpart A, to only apply to work activities that involved a physical activity (e.g., turning a valve, modifying equipment, etc.). They did not consider examinations, diagnostic evaluations, planning, or surveillance (and other such activities) to be work, and thus did not apply subpart A requirements. No work planning, hazard evaluation, procedural controls, etc., were applied to such activities. In some of these cases, such "non-work" activities involved instances in which unexpected conditions occurred, and workers received radiological exposures and intakes.

Subpart A has no limitation that work must involve physical activity or hardware. Part 830 defines quality as "…the condition achieved when an item, service, or process meets or exceeds the user's requirements or expectations." Service is defined in Part 830 as "…the performance of work, such as design, construction, fabrication, inspection, nondestructive examination/testing, environmental qualification, equipment qualification, repair, installation, or the like." Further, requirements set forth in the rule regarding record keeping, training, procurement, self-assessment, and independent assessment clearly do not require the presence of radioactive materials or "work" involving a physical activity.

Individuals who evaluate conditions, assess operations, inspect materials or equipment, evaluate problems, perform assessment activities, or other like activities are also performing work. Such work falls under the requirements of Part 830 if it pertains to a nuclear facility in which a hazard potentially exists to employees

or the general public. Since the rule applies to design, manufacture, and assembly of items for use with radioactive materials and fissionable materials, it is clear that the rule applies to such activities even if no nuclear inventory is present.

OE has also found the need, from time to time, to address a misconception that Part 830 QA requirements apply only to work that directly involves the handling of radiological material. Some implementation documents had language that said work in a nuclear facility had to have the immediate potential for radiological harm to a worker for Part 830 to apply. As noted above, Part 830 contains no such limiting applicability for work that pertains to a nuclear facility.

Attempting to limit QA requirements to situations in which only nuclear or radiological material is present in a facility.

Another applicability issue encountered by OE involved the application of Part 830 QA requirements to a radiological facility only when the facility contained an inventory of radiological material. This was based on the premise that a facility was not designated as a radiological facility until it contained radiological materials that could pose a risk to workers. The concept of when a facility becomes a radiological facility is important in terms of establishing the application of Part 835. With respect to Part 830, subpart A, the phrase "radiological facility" versus "nuclear facility" has no relevance. Part 830 applies to nuclear facilities, and for the reasons noted above, use of a threshold, such as hazard category 3, of subpart B is not applicable to a threshold for application of subpart A. In DOE's Office of General Counsel Ruling 1995-1 (61 FR 4209, February 5, 1996), the Office of General Counsel noted that "Part 830 covers activities where no nuclear material is present, such as facilities that prepare non-nuclear components of nuclear weapons, but which could cause radiological damage at a later date." (See 61 FR 4210.) Part 830 also relates to facilities that could pose a hazard to the public or the environment.

Part 830 unambiguously states that it applies to activities or operations that "[d]esign, manufacture or assemble items for use with radiological materials…." Such activities clearly fall under the requirements of the rule. Thus, the requirements of Part 830 can therefore apply to facilities and activities where no nuclear inventory is present.

Appendix I - Nuclear Weapons Program Enforcement Issues

The following guidance describes more specifically how the general enforcement process described in this Program Plan will be applied to particular conditions in the nuclear weapons program area. Section I provides a brief background of rule requirements and a related legal interpretation by DOE's Office of General Counsel as they relate to nuclear weapons programs. Section II discusses OE's general enforcement approach and the basis for making enforcement recommendations to the Administrator, NNSA. Section III addresses several specific topics concerning nuclear weapons related issues.

I. Background and Current Rule Requirements

The original version of Part 830, with an effective date of May 5, 1994, excluded in Part 830.2(c) "…activities conducted under the Nuclear Explosive and Weapons Safety Program relating to prevention of accidental or unauthorized nuclear detonations…" from the scope of the rule. Certain contractor personnel, DOE, and National Nuclear Security Administration (NNSA) representatives inappropriately interpreted this language to exempt all routine and emergency nuclear weapons related activities.

In Ruling 1995-1, the DOE Office of General Counsel (OGC) clarified this language as a narrow exclusion limited to those immediate actions necessary to prevent an accidental or unauthorized nuclear detonation. The OGC interpretation clarified that routine operations related to nuclear weapon programs were not excluded from the PAAA rules.

On January 10, 2001, DOE published an amended Part 830 final rule which removed the nuclear weapons exclusion effective April 17, 2001. Subsequent to its removal, OE received additional requests for clarification concerning the enforcement of Part 830 to nuclear weapon programs. The requests for clarification focused mainly on the six topics or issues noted below:

- Retroactive Enforcement.
- NTS Reporting of QA Deficiencies.
- Emergency Response.
- Off-Site Weapons Activities.
- Contractor QA Interfaces.
- Pre-Design R&D Work.

II. General Enforcement Approach and Guidance

OE will continue to enforce the provisions of Part 830 consistent with established enforcement policy and guidance. Nuclear facilities and activities that have the potential to cause radiological harm can be the subject of enforcement actions unless (A) specifically excluded by the rule or (B) specifically excluded through an approved exemption issued in accordance with Part 820. This includes NNSA facilities and activities that involve nuclear weapons and weapons related activities.

OE anticipates, however, the use of broad discretion in its enforcement of Part 830 based on some unique aspects involving

nuclear weapon programs. For example, OE anticipates little involvement in areas relative to nuclear weapons emergency response and activities on foreign soil. The use of this discretion is further discussed in section III.

The above described enforcement approach is consistent with the principles outlined in the Memorandum of Understanding (MOU) between the Administrator for the NNSA and the Assistant Secretary for EH, of January 12, 2001. The MOU is available at the OE webpage, http://www.eh.doe.gov/enforce.

In consideration of both the rule's applicability and the above enforcement approach, NNSA contractors, in working with the NNSA, should establish which of their facilities and activities have the potential to cause radiological harm. Contractors should then ensure those applicable facilities and activities comply with the requirements of Part 830. OE does not expect that all elements of nuclear weapon programs fall under Part 830. For instance, components that are relied upon solely for nuclear weapon reliability would not necessarily be subject to PAAA rules. Conversely, nuclear weapon activities and components that are relied upon for nuclear or radiological safety or contain radiological material most likely have the potential for radiological harm and thus would be subject to the rule.

OE is also aware that the NNSA has placed certain quality assurance (QA) requirements in its contracts, including DOE Order 414 and the QC-1 requirements of NNSA/AL Supplemental Order 56XB. OE expects that contractor processes intended to meet those QA requirements should be sufficient to demonstrate compliance with subpart A of Part 830. However, it is still incumbent on the individual NNSA contractors to review those programs and their implementation to ensure they are in compliance with subpart A.

III. Specific Enforcement Issues

A. Retroactive Enforcement

The majority of the nuclear weapons stockpile was designed, manufactured, and placed into inventory prior to the effective date of the QA rule. If quality problems are discovered, how will OE enforce the QA rule for these problems?

Quality assurance problems that were attributed to historical design and manufacturing activities conducted prior to the establishment of PAAA rules will not be subject to enforcement actions. This also applies to quality problems associated with nuclear weapon facilities, activities, and components. By establishing an effective date for each of the PAAA rules, DOE's intent was not to "backfit" the requirements of the rules to these past activities. However, the following additional points should be recognized.

Both subparts A and B of Part 830 contain requirements that currently apply to nuclear weapon programs whether or not the weapons or facilities themselves were manufactured or constructed prior to the effective date of the rule. Part 830 requirements are intended to address the ongoing management and nuclear safety of nuclear weapons and facilities (storage, stockpile surveillance, maintenance, etc.) regardless if they came into existence prior to the rule.

For example, the quality improvement criterion of subpart A requires ongoing processes to detect and correct quality problems. Failures to identify and correct safety significant

quality problems with nuclear weapons or facilities that predate the rule as part of ongoing surveillance/maintenance programs could be subject to enforcement actions. Similarly, subpart B also contains applicable requirements involving documented safety analysis (DSAs), technical safety requirements (TSRs), and USQ processes. These requirements also apply to nuclear weapon facilities and activities regardless of their design or manufacture date.

The above enforcement discretion concerning legacy quality problems is consistent with how this office addresses legacy contamination issues as outlined in section VIII.C of this Program Plan, *Enforcement Approach to Discovery and Control of Legacy Contamination Issues*.

The following example situations are provided to help illustrate the above guidance:

Example 1: A specific software code was developed and used in the design or modeling of a weapon component in 1982. This component is currently in the stockpile. Is the responsible contractor required to go back and ensure that the software code meets current quality assurance requirements?

No. OE does not expect contractors to back-fit quality requirements to processes and activities completed prior to the application date of the PAAA rules.

Example 2: A specific software code was used in the design or modeling of a component in 1982. This component is currently in the stockpile. A contractor is continuing to use this same software code for maintaining or improving the component. Is the responsible contractor required to ensure that the software or the software-generated data meets the quality assurance requirements of the rule?

Yes. If the component or activity has the potential to cause radiological harm or if it is used to prevent radiological harm, then the PAAA rules would apply since the software code or its generated data is being used for a current activity (i.e., maintenance or improvement).

Example 3: A component was designed and placed into production in 1982. It is being monitored by way of present-day surveillance activities to ensure that it continues to meet performance expectations. The monitoring activities detect a safety significant quality-manufacturing defect with the potential to cause radiological harm. Are the contractor's monitoring and corrective action activities required to meet the quality assurance requirements of the rule?

Yes. The monitoring and corrective action activities would be subject to PAAA rules and potential enforcement actions including any failures to control and correct the safety significant defects.

B. Emergency Response

A NNSA contractor may have to take certain actions during an emergency to prevent a nuclear detonation. These actions may not be in compliance with the QA rule. How will the QA rule be enforced?

The removal of the nuclear weapons exclusion from Part 830 (see section I) has resulted in questions on whether or not contractor emergency response actions could be subject to future

enforcement actions. As stated in the preamble to the October 10, 2000, Interim Final Rule, the nuclear weapons exclusion was eliminated with the addition of subpart B. Specifically, subpart B added a "safe harbor" or process for contractors to integrate both nuclear safety and nuclear explosive and weapons surety program requirements in to a single documented safety analysis (DSA). DSAs are intended to address nuclear hazard controls including emergency response programs/requirements. The preamble also stated that any potential conflicts between the different sets of requirements should be resolved by way of a rule exemption in accordance with subpart E of Part 820.

OE recognizes that in spite of the above expectations, the possibility, however unlikely, could still exist where NNSA contractors may need to take certain nuclear weapons-related emergency actions that do not comply with the rule. The primary reason for taking such actions would be the prevention of an accidental or unauthorized nuclear weapons detonation and any corresponding harm to workers, the public, and the environment.

Since these types of emergency actions are intended to prevent imminent and significant harm to workers and the public, enforcement discretion would be appropriate. The following factors, similar to those outlined in Part 830.205(b) for DOE nuclear facility emergency response activities, would be considered by OE when deciding to apply its discretion:

- The actions taken were needed to prevent an accidental or unauthorized nuclear weapons detonation and consistent with an overall intent to protect workers, the public, or the environment from imminent and significant harm.
- No other apparent and appropriate actions were available consistent with the requirements of Part 830 and corresponding implementing procedures, plans, and programs.
- The actions were authorized by the appropriate DOE/NNSA Senior Energy Official (SEO) as required.
- Follow-up corrective actions are taken as necessary to identify, report, and resolve the potential conflicts.

For noncompliances involving the above, OE will limit its enforcement authority and refrain from initiating enforcement actions.

It should be noted that OE does not intend to use its enforcement authority in a manner that inhibits or restricts contractor emergency actions essential for the protection of workers, the public, and environment from imminent and significant harm. OE also does not take enforcement action against an individual who may be involved with a PAAA noncompliance since the scope of DOE's enforcement authority is limited to the "indemnified contractor" which is a corporate entity. The exception would be a situation where criminal wrongdoing was evident.

The purpose of the enforcement program is to promote and protect the radiological health and safety of the public and workers. Consistent with the above, this office will carefully consider the facts and will exercise appropriate enforcement discretion.

The above enforcement discretion, however, does not relieve contractors of their contractual responsibilities for the management or technical support of NNSA radiological emergency response assets. It also does not relieve contractors

of their responsibility to integrate both nuclear safety and nuclear explosives and weapons surety requirements under subpart B of the rule and to address any conflicts in accordance with subpart E of Part 820.

C. Contractor QA Program Interfaces for the Design-Manufacturing-Final Assembly Cycle

The Design-Manufacture-Final Assembly (D-M-FA) cycle for nuclear weapon programs can include different NNSA prime contractors for each phase of the process. Under this arrangement, prime contractors are required to provide specialized products and services for use by other prime contractors. These prime contractors do not have contractual relationships with each other governing the QA of such services and products. How does the PAAA enforcement policy address this arrangement?

Products developed and supplied for use among different NNSA prime contractors in general represent activities performed for the DOE/NNSA. Section 830.1 of the rule states "*[t]his part governs the conduct of DOE contractors, DOE personnel, and other persons conducting activities (including providing items and services) that affect, or may affect, the safety of DOE nuclear facilities*." These shared products, including technical services and weapon components, are thus subject to the requirements of Part 830.

The NNSA, through its contracts and directives, establishes prime contractor roles and responsibilities for products used within the nuclear weapons D-M-FA cycle. Each prime contractor is therefore responsible for the quality of its NNSA-specified products used within the D-M-FA cycle including the development of a QA program in accordance with Part 830.

Based on the above arrangements, OE recognizes the potential for events to occur at one prime contractor site that discloses a potential rule noncompliances caused by a different prime contractor at another site. For example, a design flaw with a component could go undetected until the manufacturing phase of the D-M-FA cycle. As a result, OE will consider the following before determining whether or not an enforcement action is appropriate and for which specific prime contractor(s).

- Where in the D-M-FA cycle did the quality noncompliance arise and which contractor(s) was/were responsible for introducing and correcting the deficiency?
- Did the contractor(s) involved conduct the activities consistent with the requirements of the rule and their designated NNSA contractual responsibilities?
- Did the involved contractor(s) identify and voluntarily report any potential noncompliances consistent with established OE reporting guidance?
- Did the contractor discovering the issue notify other appropriate parties (other impacted contractors and NNSA/DOE officials) in a timely manner and assist in the review and corrective actions, as appropriate?
- Did the contractor responsible for the noncompliances initiate prompt and effective corrective actions?

OE also recognizes that in the contractor's delivery of products for use in the D-M-FA cycle, both formal and informal exchanges of technical support, information, and services do occur between prime contractors. In some cases, this technical exchange can

have quality assurance implications that can affect the nuclear safety of NNSA activities, including lessons learned or other similar quality related information.

It is not the intent of OE to implement its enforcement authority so as to discourage technical exchanges and communications that improve the quality of nuclear weapons services. However, because some of these technical services could significantly affect the nuclear safety of NNSA activities, contractors need to manage these services consistent with rule requirements. Contractors responsible for the generation and subsequent use of technical services must ensure they meet, in a graded approach based on safety significance, the requirements of their QA programs and the rule. This is required by the rule even if Part 830.122(g), Criterion 7-*Performance/Procurement*, is not applicable due to the lack of contractual processes between prime contractors.

The following example situations are provided to help illustrate the above guidance:

Example 1: A defect that involves nuclear safety requirements is identified in a weapon component at a NNSA production site. In evaluating the root cause of the defect, it is determined that the production site followed all quality system requirements and the deficiency was the result of a design developed by a national laboratory. In evaluating potential PAAA enforcement issues, OE will address the following lines of inquiry:

- What was the root cause of the deficiency? Was there a failure of a contractor's quality system that allowed this failure and, if so, where did this failure occur?
- Did the production site appropriately identify the defect, perform appropriate root cause analysis, and communicate the deficiency to the design lab?
- Did the design lab perform appropriate root cause analysis, reporting, and corrective action?

If the result of these questions confirmed failure at the design laboratory, then any potential enforcement actions would be assessed against the design laboratory. The manufacturing site's quality system worked correctly in identifying the defect and communication occurred between design and production contractors as desired by both NNSA and OE.

Example 2: A defect that affects nuclear safety is identified in a component produced by a supplier subcontracted by a NNSA production site. A national laboratory provided the design requirements for the component. In evaluating the root cause of the defect it is determined that the supplier produced the defect; however, the suppliers qualification and acceptance process was insufficient to prevent the defect.

In evaluating potential PAAA enforcement issues, OE will evaluate the following lines of inquiry:

- Was the design adequate? Was the design correctly provided to the NNSA production site?
- Did the production site effectively transmit design and production QA procurement requirements to the supplier?
- Was there a failure in the suppliers QA process that allowed the defective component to be purchased by the production site?
- Did the production site's quality acceptance process perform

correctly in identifying the defect?

- Was there communication and cooperation between the design and production sites in identifying, reporting, and correcting the deficiency?

OE could take enforcement action against the supplier for a failed quality control program, dependent on the responses to the above questions.

Example 3: A defect that affects nuclear safety is generated during the manufacturing process at a production site. The defect is not detected by the production site's QA program and the component is shipped to an assembly plant where the defect is detected during assembly. The assembly plant follows their work direction in identifying the non-conformance to the production site.

In evaluating potential PAAA enforcement issues, OE would evaluate the production site's quality system, the failure of the quality system to identify the defect, root cause analysis, and corrective actions taken subsequent the notification of the defective component. OE would note that the assembly plant's QA program performed correctly in identifying the defect and in communicating the defect to the originator for corrective action.

D. NTS Reporting of QA Deficiencies

The nuclear weapons complex has established QA processes for identifying, documenting, evaluating, and reporting nonconforming items. Are all of these nonconformance reports (NCRs) considered to be PAAA NTS reportable noncompliances?

OE recognizes that weapon programs have established processes to identify nonconformances to quality requirements. These processes identify quality deficiencies for weapon components and services concerning both product reliability (fit, form, and function) as well as nuclear or radiological safety. Consequently, only some of the NCRs may represent PAAA rule noncompliances and only a subset of these more significant noncompliances would meet the thresholds for PAAA NTS reporting.

Section IV. C. of this plan contains general NTS reporting guidance and appendix A contains specific NTS reporting thresholds. Contractors responsible for reporting weapons related noncompliance should refer to and use the above guidance and reporting thresholds. In determining whether or not an NCR (or any other type of deficiency/problem) represents a PAAA noncompliance that should be considered for NTS reporting, the following screening criteria should be considered:

- The NCR involves a component that has the potential for radiological harm, including specific weapon design or operational characteristics.
- The nonconformance deficiencies represent a noncompliance with a requirement of a PAAA rule.
- The noncompliance represents a programmatic or recurrence issue.
- The noncompliance meets any of the ORPS thresholds listed in appendix A of this plan.
- The noncompliance represents a willful or intentional violation of the rule.

Identified rule noncompliances that do not meet any of the NTS

reportable thresholds noted in appendix A, should be tracked locally and appropriately corrected consistent with existing contractor issue/deficiency management processes and their own PAAA program.

Note: Safeguards and Security classified information should not be included in the NTS report. The information in the NTS report should be provided so as to identify that a potential PAAA noncompliance has occurred without compromising sensitive or classified information.

The following example situations are provided to help illustrate how PAAA NTS reporting interfaces with nuclear weapon program NCR processes:

Example 1: A reservoir vessel is produced to contain tritium gas in a weapon assembly. A nonconformance with the reservoir vessel is detected during acceptance testing activities associated with the contractor's QC-1 program. The nonconformance involves an out-of-spec dimension that is an isolated case (i.e., not a reoccurring nor programmatic issue) that was detected by the functioning contractor's QA program. Although the nonconformance is reported under the NNSA weapons QC-1 program, it would not be PAAA NTS reportable.

Example 2: The same reservoir vessel is produced as noted above to contain tritium gas in a weapons assembly. A nonconformance that could create a potential for tritium gas release to a worker or the atmosphere is detected by the contractor's QC-1 program. The nonconformance has been repetitive in nature indicating an ongoing concern with the QA of the seals. The nonconformance should be considered (using the screening criteria and reporting threshold guidance noted above) for PAAA noncompliance reportability in addition to any NCR.

E. Off-Site Weapons Activities

NNSA contractor nuclear weapons program support may be required at DOD facilities and within other countries where the NNSA contractor may have no control over the facilities or conditions. How will Part 830 be enforced in these situations?

In determining whether enforcement discretion would be appropriate for the above circumstances, OE considered the following:

Subpart B of Part 830 is limited to DOE facilities and, therefore, would not apply at non-DOE/NNSA facilities, including those operated by the DOD or a government of another country.

Subpart A of the rule, however, is not limited to activities performed at DOE nuclear facilities. In the preamble (page 1811) of Part 830 Final Rule, dated January 10, 2001, DOE states the following in discussing its intent in choosing not to limit the applicability of the rule to "on-site activities":

> "*In adopting this option to cover offsite activities, we noted that the scope of the rule would apply not only to prime contractors responsible for a nuclear facility, but also subcontractors, suppliers, and other contractors including those who provide items…or services… that affect, or may affect, the nuclear safety of DOE nuclear facilities.*"

DOE's Office of General Council (GC), in its Ruling 1995-1, provided the following interpretation:

"*Although the requirements of Parts 830 and 835 apply to arrangements other than contracts, civil penalty assessments are authorized only for a '…person who may conduct activities under contract with the Department of Energy…' and any subcontractor or supplier thereto. Civil penalties are not authorized for activities conducted under a cooperative agreement, grant, or work-for-others arrangement, as distinguished from a contract.*"

The DOE Enforcement Policy of Part 820 appendix A, section IX, b. 9, *Exercise of Discretion*, states:

"*DOE will not issue a Notice of Violation for cases in which the violation discovered by the DOE contractor cannot be reasonably linked to the conduct of that contractor….*"

Based on the above, OE has determined it will generally refrain from issuing enforcement actions for Part 830 noncompliances involving off-site weapons support activities for the following reasons:

- Subpart B of the rule would not be applicable.
- DOE's original intent for expanding the scope of subpart A was to capture off-site activities that could affect the nuclear safety of DOE facilities versus regulating all off-site activities such as work at non-DOE/NNSA sites involving other agencies or governments.
- The DOE GC's 1995-1 ruling prohibits the issuance of civil penalties involving cooperative agreements or work-for-other arrangements.
- Contractor support work at non-DOE/NNSA sites typically includes conditions that are beyond the contractor's control.

F. Pre-Design R&D Work

During the research and development stage conceptual designs are evaluated and not all quality assurance requirements are applied. At what point in the R&D design process will OE start to enforce QA requirements?

Pre-design testing and engineering activities could have a significant impact on later design selection and its safety adequacy. Because of this, the requirements of Part 830 were written to address the QA of design items and processes including pre-design selection activities. Specifically, Part 830.122(f)(5) states "[v]erify or validate work before approval and implementation of the design." It is also recognized that not all QA requirements of the rule would apply to all of the varying types of pre-design testing and selection activities.

Based on the above, there exists no consistent or defining point in the design process for commencing implementation of the QA rule or enforcement actions. Contractors should therefore consider the use of a graded approach versus defining a specific point (design approval) for commencing QA rule implementation. The graded approach should be based on the impacts the pre and post-design selection activities have on the safety adequacy of the final design selected and implemented.

Consistent with the above-described approach, OE intends to only investigate and issue enforcement actions concerning design-related noncompliances with safety related consequences. In general, OE will therefore limit its enforcement actions only to noncompliances involving implemented designs (post-design selection failures). It should be noted, however, that even though the enforcement action may be issued for a

post-design selection failure, the noncompliance cited could be based on a pre-design selection failure such as that described in Part 830.122(f)(5) (see above).

Discussed below are various anticipated design-related failures/deficiencies and the manner in which OE would assess these events (in recognition of above rule applicability and graded approach) for potential QA rule noncompliances and enforcement actions.

Post-design selection and implementation failures: A weapon component fails and the component is one that is critical to preventing significant radiological harm. The component failure was attributed to an inadequate design caused by inadequate safety related performance tests conducted during the pre-design selection process. OE would consider this type of failure for potential enforcement actions due to a noncompliance involving a failure to verify/validate work (inadequate testing) prior to design approval and the event consequences (significant radiological harm).

Pre-design selection component QA failures/deficiencies: Several prototype vessels are being considered for use in a future weapon to contain a radioactive gas. The components have different sealing designs and are being subject to leak testing using a surrogate non-radioactive gas. Several of the designs fail the leak test and do not meet the quality performance criteria established for the test. None of the failed prototype designs were selected for further use. The testing was conducted in a non-nuclear and non-radiological facility. OE would not consider the above types of events for potential enforcement actions since the failed prototype activity was not part of the design process for components to be used in a nuclear weapon, facility, or activity.

Pre-design selection activity failures/deficiencies: Design R&D activities are being conducted involving neutron flux testing on prototype components using a research reactor. The described R&D activities would be subject to potential enforcement actions since the R&D involves nuclear activities with the potential to cause radiological harm (i.e., flux testing using a nuclear reactor).

Appendix J – Legacy Contamination

The concept of legacy, or pre-existing, contamination is neither defined nor discussed in Part 835 (both original and amended versions). Further, no exclusions for pre-existing conditions (including legacy contamination) are contained in Part 835, subpart A. Consequently, the identification of any radioactive surface contamination (legacy or otherwise) above the applicable levels contained in Part 835, appendix D, for an unposted and uncontrolled area typically represents a noncompliance with Part 835 requirements. The specific noncompliance with Part 835 would vary based on the circumstances of the discovery. However, the following sections would generally be applicable:

- 835.603(e) - Requires that Contamination Areas (see 835.2 definition) be posted.
- 835.1102(b) - Requires that areas where contamination levels exceed appendix D values be appropriately controlled.
- 835.1102(c) - Establishes control requirements for areas where fixed-only contamination levels exceed appendix D values.

Such discoveries may also represent a noncompliance with Part 830.122, *Quality Assurance Criteria*, depending upon circumstances and specific procedural requirements.

It should be recognized during evaluations of legacy contamination conditions that the appendix D values of Part 835, which trigger the above requirements, are applicable to surface contamination conditions only. They do not apply to situations in which an item or area is contaminated only in volume or by matrix (see note 1 to appendix D, also see the Part 835 preamble comment on volumetric contamination in 58 FR 65475). Consequently, the discovery of an item incorporating legacy contamination by volume but not representing a surface contamination condition or hazard (such as contaminated flora, fauna, or some soils[1]) would not typically represent a Part 835 noncompliance. Despite this, Part 835 non-applicability, such environmental contamination conditions, must be appropriately controlled. It should also be noted that environmental contamination may present other radiological hazards (such as direct radiation) that do require appropriate posting and control under Part 835.

In recognition of the specific circumstances that surround a legacy contamination discovery event, OE generally does not pursue enforcement for a noncompliance identified in association with such events, subject to the following conditions:

- An effective radiological survey program is in place and functioning.
- Appropriate and timely corrective actions (such as posting, effective area control, decontamination, etc.) are taken upon identification of the contamination.

[1] For the case of volume-contaminated soil, the applicability of the Part 835, appendix D, levels are based on the potential to disperse contamination from the area in excess of these levels. If such a potential is likely, the area containing the soil should be posted and controlled as a Contamination Area. DOE relevant guidance is contained in Implementation Guide DOE G 441.1-9, *Radioactive Contamination Control Guide*, (6/99) and Article 238.3 of the DOE Standard DOE-STD-1098-99, *Radiological Control*, (12/04).

- It is unreasonable to expect the contamination to have been identified earlier, either through implementation of the radiological survey program, the review of readily available historical information, or the prudent response to previous contamination incidents.

Even though the condition may warrant OE discretion in terms of enforcement action per the above, the condition may still qualify for reporting into the NTS. Contamination events (legacy or otherwise) should be screened and tracked in accordance with existing site PAAA program procedures. Typically, simple discovery-type events would not meet NTS reporting thresholds and should be entered into and tracked on contractor local noncompliance tracking systems. For those contamination-related noncompliances meeting the thresholds of tables A-1 or A-2 of appendix A, a report should be made to the NTS regardless of whether the contractor chooses to apply the term "legacy."